EPA Reg. No. 1677-241

Material Sent for Data Extraction

Reg. # 1677-241

Description: new registration

☒ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 9/17/2013
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Nathan Moffi

Phone: 305-0208 Division: AD

Date: 9/17/2013

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
1677-241	SEP 17 2013

Term of Issuance: **Conditional**

Name of Pesticide Product: Hydris

NOTICE OF PESTICIDE:
x Registration
__ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ted Head
Ecolab, Inc.
655 Lone Oak Drive
Eagan, MN 55121

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling.

Signature of Approving Official:

PM Name
Product Manager Team
Regulatory Management Branch
Antimicrobials Division (7510P)

Date: SEP 17 2013

EPA Form 8570-6

Hydris™

Disinfectant, Sanitizer, Virucide, Fungicide, Mildewcide, Bactericide, Cleaner, Deodorizer

Active Ingredients:

Sodium Hypochlorite	0.0866%
Inert Ingredients	99.9134%
Total	100.00%

Available Chlorine: 0.0825% Free Available Chlorine FAC

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Harmful if absorbed through skin or swallowed Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Mixing this product with acid or ammonia will release chlorine gas.

Do not mix solution with other cleaning products.

Do not use solution with acidic toilet-bowl cleaners, or bathroom/shower cleaning products.

Do not use solution on wool or natural carpet fibers.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Solution(s) are efficacious for up to 7 days from filling. After 7 days, empty and refill with fresh solution. Always use a clean Hydris™ spray bottle when filling this product.

Solution can be used immediately or stored in a closed Ecolab approved container in a cool, dark area for a period of 5 months. Once opened within this time period, the solution must be used immediately.

Hydris™ Disinfectant Cleaner is intended for use in commercial, institutional and hospitality housekeeping. It cleans, deodorizes and kills germs in one step.

Hydris™ Disinfectant Cleaner is an activated aqueous solution of sodium hypochlorite produced by passing a brine solution through an electrolytic cell and changing the properties of the salt water into an oxidizing agent exhibiting antimicrobial properties. The **Hydris™ Disinfectant Cleaner** is dispensed by the Ecolab Hydris dispenser at both 825 ppm Free Available Chlorine and 260 ppm Free Available Chlorine as noted on the dispenser. No further dilution is required.

Hydris™ Disinfectant Cleaner is designed for use in

Hotel/motel housekeeping

Commercial building routine cleaning of hard surfaces and floors.

Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.

Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.

Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

Cleaning and disinfecting hospitals, assisted living facilities, long term care centers, nursing homes and medical clinics.

Spray solution onto hard, non-porous surface, thoroughly wetting surfaces, Hold sprayer 6-8 inches from the surface. Spread solution with a disposable, cotton or microfiber wipe, sponge, or cloth. Allow surface to remain wet for time indicated. No rinsing necessary.

BACTERICIDAL / DISINFECTANT in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria according to the AOAC Germicidal Spray Test in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Acinetobacter baumannii (ATCC 19606), *Acinetobacter baumannii* (MDR) (ATCC BAA-1605), *Escherichia coli* (ATCC 11229), *Klebsiella pneumonia* (ATCC 4352), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Serratia marcescens* (ATCC 14756), *Shigella flexneri* (ATCC 9380), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus aureus* (VISA) (ATCC 700788), *Staphylococcus aureus* (CA-MRSA) (ATCC BAA - 1683), *Staphylococcus aureus* (MRSA) (ATCC 33592), *Klebsiella pneumonia (Carapenum-resistant)* (ATCC BAA-1705), *Enterobacter aerogenes* (ATCC 13048),*Enterococcus faecalis* (ATCC 29212), *Streptococcus pyogenes* (ATCC 19615), *Shigella dysenteriae* (ATCC 29026), *Listeria Monocytogenes* (ATCC 7644).

BACTERICIDAL / DISINFECTANT in 10 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Enterococcus faecalis (VRE) (ATCC 51299) and *Escherichia coli* 0157:H7(ATCC 43895)

NON-FOOD CONTACT SURFACE SANITIZING in 1 minutes 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

NON-FOOD CONTACT SURFACE SANITIZING in 4 minutes at 273 ppm sodium hypochlorite (260 Free Available Chlorine) in 250 ppm hard water against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

VIRUCIDAL in 30 seconds at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Influenza A virus H1N1Strain (ATCC VR-1736), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Murine Norovirus (Strain MNV-1.CW1), Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Herpes Simplex Virus Type I (ATCC VR-733 Strain F), Herpes Simplex Virus Type II (ATCC VR-734, Strain G), HIV-1 (Strain HTLV-III_B).

VIRUCIDAL in 30 seconds at 273 ppm sodium hypochlorite (260 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum and 400 ppm hard water on hard, non-porous surfaces against the following organisms.

Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Influenza A virus H1N1Strain (ATCC VR-1736),

VIRUCIDAL in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Adenovirus Type 5 (ATCC VR-5), Hepatitus B Virus (HBV), Human Coronavirus (ATCC VR-740), Respiratory Syncytial Virus (RSV) (ATCC VR-26), Rotavirus (Strain WA), Vaccinia Virus (ATCC VR-119).

FUNGICIDAL in 10 minutes at 866 ppm sodium hypochlorite 825 ppm Free Available Chlorine) according to the AOAC Fungicidal Test in the presence of 5% blood serum on hard, non-porous surfaces against *Trichophyton mentagrophytes* (ATCC 9533), and *Aspergilus niger* (ATCC 6275).

DEODORIZER Apply solution with sprayer, cloth, mop, auto-scrubber, or carpet extractor to surfaces harboring odor-causing bacteria.

STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: RESIDUE REMOVAL INSTRUCTIONS: For containers less than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

Net Contents:

Manufactured by:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-[pending]
EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 5389-NC-(G) 1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V),

58046-TX-2 (X)

Superscript refers to first letter of date code

Optional Marketing Language

- Cleans every day dirt and soils from surfaces
- Deodorizes – or - Deodorizer
- Easy to use
- Eliminates odors
- Eliminates odors caused by [bacteria] [germs] [mildew]
- Leaves [bathroom(s)] [restroom(s)] [locker room(s)] [surfaces][clean and] sanitary
- Leaves behind a fresh clean smell – or - fragrance
- Low odor [formula – or- profile]
- No PPE [Personal Protective Equipment] required
- No rinsing necessary
- One-step cleaner [and disinfectant]
- Removes –or- eliminates odors [at the source]
- Streak-free [formula –or- clean]
- Effective against odor causing bacteria
- [This product is] VOC [Volatile Organic Compounds] compliant
- [This product] Contains no NPEs [Nonylphenol ethoxylates]
- [This product is] Phosphate free
- Leaves surfaces sanitized
- Sanitizer
- Sanitizes surfaces
- Sanitizes hard, nonporous surfaces
- Antibacterial [action]
- Bacteria-fighting - or – Germ-fighting formula
- Bactericide – or Bactericidal
- Restroom – or- bathroom disinfectant
- Broad spectrum disinfectant [cleaner]
- Cleans and disinfects
- Cleans and disinfects within 5 minutes Cleaner and disinfectant in one
- Cleans – and/or – disinfects [bathroom] [school] [classroom] [restroom] [locker room] [office] [work – or- office place] [environment] [place] [surfaces] [floors] [table – or- desk tops] [hard surfaces] [railings] -and/or- deodorizes
- Disinfects
- Disinfects and deodorizes by killing common [germs – or – bacteria] and controlling their odors

- Disinfects as it cleans
- Disinfects nonporous [hard] surfaces
- Easily [cleans] [deodorizes] [sanitizes] [disinfects]
- [Effective] disinfectant [in the presence of 5% serum load – or – organic soil]
- Germicide – or Germicidal
- Institutional disinfectant
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] –and/or – destroy[s] [the] cold virus – and/or – flu virus – and/or – cold and flu virus[es] – and/or viruses that can cause cold - and/or flu
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] – and/or- and/or – destroy[s] Methicillin-resistant Staphylococcus aureus [(MRSA)] –and/or – Community Acquired Methicillin-resistant Staphylococcus aureus [(CA-MRSA)]
- Kills cold and flu virus
- Kills germs while it cleans
- Kills Pandemic 2009 H1N1 Influenza A virus [(formerly called swine flu)]
- Multipurpose disinfectant
- One-step cleaner [and disinfectant]
- Antifungal
- Fungicidal –or- Fungicide
- Kills mold and mildew
- Kills athlete's foot fungus
- Mildewcidal –or- Mildewcide
- Removes –and/or – cuts through – and/or- tough on mold –and/or mildew
- Disinfectant
- Non-Food Contact Sanitizer
- Effective in the Presence of 5% organic soil Contamination
- One-step Disinfectant/Cleaner
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Hospital Disinfectant
- Sanitizer
- Effective in the Presence of 5% organic soil contamination
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Effective One-step Sanitizer/Cleaner in hard water up 250 ppm hardness.
- Commercial building routine cleaning of hard surfaces, including glass/mirror surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.
- Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.

- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.
- Commercial building routine cleaning of hard surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

USE LOCATIONS: [Where to use this product] [For use around – or- in –or- throughout the]

- Assisted Living Facilities
- Athletic Facility[Facilities]
- Bathroom[s]
- Business[es]
- Commercials Building[s]
- Daycare Center[s] –or- Childcare Center[s]
- Fitness Center[s]
- Government Building[s]
- Health Club[s]
- Healthcare [facilities]
- Hospital[s]
- Hotel[s]
- Institutions
- Laboratories
- Lodging
- Locker Room[s]
- Long Term Care Center[s]
- Medical Facilities
- Motel[s]
- Office[s] [Buildings]
- Patient Care Area[s]
- Recreational Center[s] –or- Facility [Facilities]
- Retail Center[s]
- School[s] –an/or University[Universities] – and/or- Colleges

USE SITES: [For] Use on [hard,] [nonporous surface] – or - The product will not damage-or- harm

- [Bath] Tubs
- [Classroom] Desks
- Countertops
- Counter[s]
- Diaper Changing Table[s]
- Diaper Pail[s]
- [Door] Knobs
- Elevator[s]
- Fixture[s]
- Examination Tables –and/or- Beds
- Floors
- Glass –and/or- Mirror Surfaces
- Hard [Non-porous] Surfaces
- High-Touch Point[s]
- Patient Bed[s] –and/or Rail[s]
- [Play] Tables[s] –and/or- Stations
- Shower Curtain[s]
- Shower stall[s]
- Shower[s]
- Sink[s]
- Table[s]
- Toilet[s]
- Urinal[s]
- [Water] [Drinking] Fountain
- [Washable] Chair[s]
- [Washable] Walls

USE SURFACES:

- ABS [Acrylonitrile butadiene styrene] [plastic]

- Aluminum
- [Brushed] [Polished] Nickel
- [Brushed] Bronze
- Carpet (50 ppm FAC –or- 52 ppm sodium hypochlorite solution only), test in an inconspicuous spot first
- Glass
- Sealed Granite
- Hard, non-porous surfaces –or environmental surfaces
- Limestone
- Melamine
- Mirror
- [Polished] Chrome
- Polyacrylic
- Polycarbonate
- Polyethylene
- Polypropylene
- Slate
- Stainless Steel [304]
- Terrazzo
- To avoid possibility of discoloration, avoid prolonged contact of the 825 ppm FAC or 866 ppm sodium hypochlorite solution with certain metals (such as brass, steel), and marble surfaces.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

August 26, 2013

MEMORANDUM

Subject: Efficacy Review for Hydris™
EPA Reg. No. 1677-EUR
DP Barcode: D412101

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Michael Mendelsohn, PM 32/ Nathan Mottl
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Ecolab
370 Wabash Street North
St.Paul, MN 55102-1390

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	0.0866%
Inert Ingredients	99.9134%
Total	100.0000%

I. BACKGROUND

The product Hydris™ is a new registration. It is a disinfectant (bactericide, virucide, fungicide) and non-food contact sanitizer for use on hard non-porous surfaces in commercial institutional, and hospitality housekeeping settings. The Hydris use dilution is generated in conjunction with the Hydris Mineral Activator Tablet and a pesticide device (three-chamber electrolytic cell) to produce the Hydris sodium hypochlorite solution generated onsite with no resale or distribution. Studies were conducted by Ecolab, Ecolab Schuman Campus, 655 Lone Oak Drive, Eagan, MN 55121-1560 and ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained: a letter from the registrant (dated March 25, 2013), Data Matrix (EPA Form 8570-35), a proposed product label and twenty three efficacy studies (MRID 490895-06 through -28) with a Statement of No Data Confidentiality Claims embedded in each study.

II. USE DIRECTIONS

The product, Hydris™ is intended to be used as a disinfectant and sanitizer on hard, non-porous, non-food contact surfaces including bath tubs, classroom desks, countertops, diaper changing tables, door knobs, elevators, examination tables, floors, glass, patient beds, shower stalls, toilets, urinals, and walls.

The draft label provides the following generic use directions: Spray solution onto hard, non-porous surface, thoroughly wetting surfaces. Hold sprayer 6-8 inches from the surface. Spread solution with a disposable, cotton or microfiber wipe, sponge, or cloth. Allow surface to remain wet for time indicated. No rinsing necessary.

BACTERICIDAL / DISINFECTANT: in 5 and 10 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against pathogenic bacteria listed on the label in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces.

VIRUCIDAL: in 30 seconds at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non- porous surfaces against the following organisms:

> Influenza A virus H1N1Strain (ATCC VR-1736), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Murine Norovirus (Strain MNV-1.CW1), Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Herpes Simplex Virus Type I (ATCC VR-733 Strain F), Herpes Simplex Virus Type II (ATCC VR-734, Strain G), HIV-1 (Strain HTLV-III_B).

VIRUCIDAL: in 30 seconds at 273 ppm sodium hypochlorite (260 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum and 400 ppm hard water on hard, non-porous surfaces against the following organisms:

> Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Influenza A virus H1N1 Strain (ATCC VR-1736),

VIRUCIDAL: in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non- porous surfaces against the following organisms:

> Adenovirus Type 5 (ATCC VR-5), Hepatitus B Virus (HBV), HumaCoronavirus (ATCC

VR-740), Respiratory Syncytial Virus (RSV) (ATCC VR-26), Rotavirus (Strain WA), Vaccinia Virus (ATCC VR-119).

FUNGICIDAL: in 10 minutes at 866 ppm sodium hypochlorite 825 ppm Free Available Chlorine) according to the AOAC Fungicidal Test in the presence of 5% blood serum on hard, non-porous surfaces against *Trichophyton mentagrophytes* (TCC 9533), and *Aspergillus niger* (ATCC 6275).

III. AGENCY STANDARDS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers] To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Salmonella enterica* ATCC 10708 and *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. Brief Description of the Data

1. MRID 490895-06 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus 37-260 ppm." Test Organism: Rhinovirus 37, strain 151-1 ATCC VR-1147, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-2. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 19, 2012. Study ID Number 1200063.

This study was conducted using two lots of Aqualogic Lots 051512DT-2 (batch 2) and 052912DT-2 (batch 2), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Rhinovirus Type 37-260 ppm (strain 151-1 ATCC VR-1147), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200063 (copy provided). The host cell line was HeLa cells (ATCC CRL-2)

which were prepared from the third or greater transfer to 24 well assay plates, incubated at 35±2°C at 5±2% CO_2 for two days. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 50-100 IU penicillin and 50-100 µg/mL streptomycin. The two lots of test substance were diluted to 260 ppm free available chlorine in sterile 400 ppm synthetic hard water. Lot 051512DT-2 dilution 97.85 g test substance plus 252.15 g diluent and Lot 052912DT-2 dilution 100.10 g test substance plus 249.91 g diluent to achieve 260 ppm available chlorine. Several vials of stock virus culture of Rhinovirus Type 37-260 ppm was thawed and pooled on the day of the test and since 5% Fetal Bovine Serum (FBS) is present in the virus stock, no additional soil load was added. The bottom of 100×15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 30-33 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls. The test was conducted at ambient (15°-30°C) temperature. Near the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700×g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

2. MRID 490895-07 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus 37-660 ppm." Test Organism: Rhinovirus 37, strain 151-1 ATCC VR-1147, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-2. Study Director Lisa Hellickson. Study conducted byEcolab. Study completion date, Dec 19, 2012. Study ID Number 1200062.

This study was conducted using two lots of Aqualogic Lots 051512DT-2 (batch 2) and 052912DT-2 (batch 2), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Rhinovirus Type 37-660 ppm (strain 151-1 ATCC VR-1147), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200062 (copy provided). The two lots of test substance were diluted to the lower certified limit of 660 ppm available chlorine in sterile lab purified water. Lot 051512DT-2 dilution 248.00 g test substance plus 102.00 g diluent and Lot 052912DT-2 dilution 253.76 g test substance plus 96.25 g diluent to achieve 660 ppm available chlorine. The host cell line was HeLa cells (ATCC CCL-2) which were prepared from the third or greater transfer to 24 well assay plates, incubated at 35±2°C at 5±2% CO_2 for two days. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 50-100 IU penicillin and 50-100 µg/mL streptomycin. Several vials of stock virus culture of Rhinovirus Type 37-660 ppm was thawed and pooled on the day of the test and since 5% Fetal Bovine Serum (FBS) is present in the virus stock, no additional soil load was added. The bottom of 100 x 15 mm glass petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 32-35 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls. The test was conducted at ambient (15° - 30° C) temperature. At the end of the 30 second exposure time, the dried film was scraped from the surface of the dish

with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700×g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted in test medium to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

3. MRID 490895-08 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Feline Calicivirus as a Surrogate for Norovirus -660 ppm". Test Organism: Feline Calicivirus, strain F-9 ATCC VR-782, for product Aqualogic, Lot Numbers 051512DT-2, 051512DT-3 and 052912DT-1. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 20, 2012. Study ID Number 1200066.

This study was conducted using two lots of Aqualogic (Lots 051512DT and 052912DT), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Feline Calicivirus (strain F-9 ATCC VR-782), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200066 (copy provided). Lot 051512DT-3 (batch 3 tested 07/17/12) dilution 246.96 g test substance plus 103.05 g diluent, Lot 052912DT-1 (batch 1 tested 07/17/12) dilution 253.75 g test substance plus 96.26 g diluent, Lot 051512DT-2 (batch 2 tested 08/03/12) dilution 215.12 g test substance plus 84.85 g diluent and Lot 051512DT-2 (batch 2 tested 08/09/12) dilution 213.95 g test substance plus 86.04 g diluent to achieve 660 ppm available chlorine. The host cell line was CRFK cells (ATCC CCL-94) which was prepared from the third or greater transfer to 24 well assay plates, incubated at 35±2°C at 5±2% CO_2 for two days. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 50-100 IU penicillin and 50-100 µg/mL streptomycin. The two lots of test substance were diluted to the lower certified limit of 660 ppm available chlorine in sterile laboratory purified water. Several vials of stock virus culture of Feline Calicivirus was thawed and pooled on the day of the test and since 5% horse serum is present in the virus stock, no additional soil load was added. The bottom of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried in a biological safety cabinet for 38 minutes on 07/17/12, 35-36 minutes on 08/03/12 and 38 minutes on 08/09/12. Each batch of use-solution was dispensed into one glass petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at ambient (15° - 30° C) temperature. At the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700 x g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted in test medium to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7-10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

4. MRID 490895-09 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Feline Calicivirus as a Surrogate for Norovirus -260 ppm". Test Organism: Feline Calicivirus, strain F-9 ATCC VR-782, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-2. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 20, 2012. Study ID Number 1200067.

This study was conducted using two lots of Aqualogic, Lots 051512DT-2 (batch 2) and 052912DT-2 (batch 2), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Feline Calicivirus (strain F-9 ATCC VR-782), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200067 (copy provided). The two lots of test substance were diluted to the lower certified limit of 260 ppm available chlorine in 400 ppm sterile synthetic hard water. Lot 051512DT-2 dilution 84.85 g test substance plus 215.12 g diluent and Lot 052912DT-2 dilution 87.05 g test substance plus 212.95 g diluent to achieve 260 ppm available chlorine. The host cell line was CRFK cells (ATCC CCL-94) which was prepared from the third or greater transfer to 24 well assay plates, incubated at 35±2°C at 5±2% CO_2 for two days. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 50-100 IU penicillin and 50-100 µg/mL streptomycin. Several vials of stock virus culture of Feline Calicivirus were thawed and pooled on the day of the test and since 5% horse serum is present in the virus stock, no additional soil load was added. The bottom of 100 x 15 mm glass petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried in a biological safety cabinet for 35 minutes. Each batch of use-solution was dispensed into one glass petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at ambient (15° - 30° C) temperature. At the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700 x g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted in test medium to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7-10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

5. MRID 490895-10 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Herpes Simplex Type 1." Test Organism: Rhinovirus 37, strain F (1) ATCC VR-733, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-2. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 12, 2012. Study ID Number 1200064.

This study was conducted using two lots of Aqualogic Lots 051512DT-2 (batch 2) and 052912DT-2 (batch 2), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Herpes Simplex Type 1 (strain F (1) ATCC VR-733), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200064 (copy provided). The host cell line of Vero Cells (ATCC CLL-81) was prepared from the third or greater transfer to 24 well assay plates, incubated at 35±2°C at 5±2% CO_2 for two days. Test medium used to maintain the cell cultures was Minimum Essential Medium,

Eagle (EMEM) test medium, supplemented with 50-100 IU penicillin and 50-100 µg/mL streptomycin. The two lots of test substance were diluted to the lower certified limit of 660 ppm available chlorine in sterile Milli-Q water. Lot 051512DT-2 dilution 314.13 g test substance plus 135.85 g diluent and Lot 052912DT-2 dilution 327.30 g test substance plus 122.66 g diluent to achieve 660 ppm available chlorine. Several vials of stock virus culture of HSV Type 1 were thawed and pooled on the day of the test and since 5% Fetal Bovine Serum (FBS) is present in the virus stock, no additional soil load was added. The bottom of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 40-43 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls. The test was conducted at ambient (15° - 30° C) temperature. At the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700 x g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted in test medium to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7 to 10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

6. MRID 490895-11 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza A Virus -260 ppm." Test Organism: Influenza A Virus H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-3. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 12, 2012. Study ID Number 1200061.

This study was conducted using two lots of Aqualogic Lots 051512DT-2 (batch 2) and 052912DT-3 (batch 3), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200061 (copy provided). Assay plates seeded with Rhesus Monkey Kidney cells (RMK) were purchased from ViroMed Labs and were incubated at 35±2°C at 5±2% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 100 units/mL penicillin, 10 µg/mL gentamicin, 2.5 µg/mL fungizone, 10 mM Hepes, SV% & SV40 antisera. The two lots of test substance were diluted to 260 ppm free available chlorine in sterile 400 ppm synthetic hard water. Lot 051512DT-2 dilution 85.58 g test substance plus 215.42 g diluent and Lot 052912DT-3 dilution 86.85 g test substance plus 213.13 g diluent to achieve 260 ppm available chlorine. Two vials of stock virus culture of Influenza A Virus were thawed and pooled on the day of the test. Fetal Bovine Serum (FBS) was added to obtain a 5% soil load (0.1 mL FBS, 1.9 mL pooled virus). The bottom of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 32-35 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at ambient (15°-30°C) temperature. Near the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged

for 2 minutes at 700 x g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7-10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

7. MRID 490895-12 "Aqualogic Germicidal Spray Hospital Disinfection Efficacy" for the product Aqualogic. Study director is Lisa Hellickson. Study conducted by Ecolab. Study completion date – December 17, 2012. Project Number 1200052.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) and *Salmonella enterica* (ATCC 10708). Three lots (051512DT, 052912DT, 050112DT (≥60 days old)) of the product, Aqualogic, was tested using Ecolab Microbiological Services SOP Method MS010-20 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified or Milli-Q water to yield 660 ppm available chlorine as follows:

Lot 51512DT-1; 1054.33g + 445.68 g diluent = 660 ppm available chlorine
Lot 52912DT-1; 1077.96g + 422.05g diluent = 660 ppm available chlorine
Lot 50112DT-1; 1072.12g + 427.85g diluent = 660 ppm available chlorine
Lot 50112DT-2; 431.59g + 168.40g diluent = 660 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. Transfers were performed daily, but the last transfer prior to the conduct of the test were 24 ± 4 hour transfers. The culture used in the test was grown in 20 mL of culture medium, vortexed, and allowed to settle for 10 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty glass slide carriers were inoculated with 0.01 mL of a suspension of test organism. The carriers were dried for 30 to 40 minutes at 35±2°C. Each carrier was sprayed with the test product until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at ambient temperature (15-30°C). Following exposure, individual carriers were transferred to Letheen Broth containing 5% sodium thiosulfate to neutralize. All subcultures were incubated for 48±4 hours at 35±2°C. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population.
Note: Protocol deviations/amendments reported in this study report were reviewed and found to be acceptable.

8. MRID 490895-13 "Aqualogic Non-Food Contact Surface Sanitizing Efficacy 4 Minutes Exposure Time" for the product Aqualogic. Study director is Lisa Hellickson. Study conducted by Ecolab. Study completion date – May 18, 2012. Project Number 120-054.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (051512DT, 052912DT, 050112DT (≥60 days old)) of the product, Aqualogic, was tested using Ecolab Microbiological Services SOP Method MS016-23 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in 250 ppm sterile synthetic hard water to yield 260 ppm available chlorine as follows:

Lot 51512DT-1; 55.96g + 144.02g diluent = 260 ppm available chlorine

Lot 51512DT-2; 56.32g + 143.69g diluent = 260 ppm available chlorine
Lot 52912DT-2; 56.81g + 143.91g diluent = 260 ppm available chlorine
Lot 50112DT-1; 56.09g + 143.68g diluent = 260 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. Transfers were performed daily, but the last transfer prior to the conduct of the test were 24 ± 4 hour transfers. The culture used in the test was grown in 10 mL of culture medium, vortexed, and allowed to settle for 15 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five (5) 1 inch x 1 inch stainless steel carriers were inoculated with 0.01 mL of a suspension of test organism. The carriers were dried for 30 to 40 minutes at 35±2°C. The dried, inoculated carriers were aseptically transferred to sterile jars-one carrier per jar. 5 mL of each lot of Aqualogic use-solution was dispensed onto one inoculated and dried carrier at a time. Each carrier remained in contact with the product for 3 minutes for *E. aerogenes* and 4 minutes for *S. aureus* at ambient temperature (15-30°C). At the end of the exposure time, 20 mL of 2X D/E Broth was added to the jar. Each jar was then rotated on an even plane approximately 50 rotations. 1.0 mL and 0.1 mL of the neutralizer solution was plated in duplicate from each jar and pour plated with Tryptone Glucose Extract Agar. The recovery medium plates were incubated at 35 ± 2°C for 48 ± 4 hours for *S. aureus* or 30 ± 2°C for 48 ± 4 hours for *E. aerogenes*. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population.

Note: Protocol deviations/amendments reported in this study report were reviewed and found to be acceptable.

9. MRID 490895-14 "Aqualogic Non-Food Contact Surface Sanitizing Efficacy 1 Minute Exposure Time" for the product Aqualogic. Study director is Lisa Hellickson. Study conducted by Ecolab. Study completion date – December 17, 2012. Project Number 1200053.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (051512DT, 052912DT, 050112DT (≥60 days old)) of the product, Aqualogic, was tested using Ecolab Microbiological Services SOP Method MS016-23 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified or Milli-Q water to yield 660 ppm available chlorine as follows:

Lot 51512DT-1; 141.88g + 58.11 g diluent = 660 ppm available chlorine
Lot 51512DT-1; 142.80g + 57.20 g diluent = 660 ppm available chlorine
Lot 52912DT-2; 144.02g + 55.95g diluent = 660 ppm available chlorine
Lot 50112DT-1; 142.19g + 57.82g diluent = 660 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. Transfers were performed daily, but the last transfer prior to the conduct of the test were 24 ± 4 hour transfers. The culture used in the test was grown in 10 mL of culture medium, vortexed, and allowed to settle for 15 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five (5) 1 inch x 1 inch stainless steel carriers were inoculated with 0.02 mL of a suspension of test organism. The carriers were dried for 35 minutes at 35±2°C. The dried, inoculated carriers were aseptically transferred to sterile jars-one carrier per jar. 5 mL of each lot of Aqualogic use-solution was dispensed onto one inoculated and dried carrier at a time. Each carrier remained in contact with the product for 1 minute at ambient temperature (15-30°C). At the end of the exposure time, 20 mL of 2X D/E Broth was added to the jar. Each jar was then rotated on an even plane approximately 50 rotations. 1.0 mL and 0.1 mL of the neutralizer solution was plated in duplicate from each jar

and pour plated with Tryptone Glucose Extract Agar. The recovery medium plates were incubated at 35 ± 2°C for 48 ± 4 hours for *S. aureus* or 30 ± 2°C for 48 ± 4 hours for *E. aerogenes*. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population.
Note: Protocol deviations/amendments reported in this study report were reviewed and found to be acceptable.

10. MRID 490895-15 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza A Virus -660 ppm." Test Organism: Influenza A Virus H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736, for product Aqualogic, Lot Numbers 051512DT-2 and 052912DT-3. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 18, 2012. Study ID Number 1200060.

This study was conducted using two lots of Aqualogic Lots 051512DT-2 (batch 2) and 052912DT-3 (batch 3), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736), with a 5% fetal bovine serum organic soil load, after 30 seconds exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200060 (copy provided). The two lots of test substance were diluted to 660 ppm free available chlorine in sterile laboratory purified water. Lot 051512DT-2 dilution 214.41 g test substance plus 85.57 g diluent and Lot 052912DT-3 dilution 220.17 g test substance plus 79.85 g diluent to achieve 660 ppm available chlorine. Assay plates seeded with Rhesus Monkey Kidney cells (RMK) were purchased from ViroMed Labs and were incubated at 35±2°C at 5±2% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 100 units/mL penicillin, 10 µg/mL gentamicin, 2.5 µg/mL fungizone, 10 mM Hepes, SV5 & SV40 antisera. Two vials of stock virus culture of Influenza A Virus were thawed and pooled on the day of the test. Fetal Bovine Serum (FBS) was added to obtain a 5% soil load (0.1 mL FBS, 1.9 mL pooled virus). The bottom of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 34-36 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at ambient (15°-30°C) temperature. Near the end of the 30 second exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700 x g after which the supernatant was inoculated into assay plates seeded with the test cell culture (0.1 mL per well) and serially diluted to inoculate assay plates. Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7-10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

11. MRID 490895-16 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Human Immunodeficiency virus type 1, for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Shanen Conway, B.S., Study completion date, Oct. 8, 2012. Study conducted by ATS Labs. Project Number A13930.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Human Immunodeficiency virus type 1, Strain HTLV-III_B (obtained from Advanced Biotechnologies, Inc.) with a 5% fetal bovine serum organic soil load. Testing followed Protocol Number ECO01072512.HIV (copy provided). The host cell line, MT-2 cells (human T-cell leukemia cells obtained through the AIDS Research and Reference Reagent Program) was maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was RPMI-1640 supplemented with 15% (v/v) heat-activated fetal bovine serum (FBS) and with 2.0 mM L-glutamine and 50 µg/mL gentamicin. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 356.99 g test substance plus 143.01 g diluent and Batch 080112-CL1 dilution 352.78 g test substance plus 147.22 g diluent to achieve 660 ppm available chlorine. On the day use, an aliquot of stock virus HIV type 1 (strain HTLV-III_B) was thawed and adjusted to contain 5% FBS as the organic soil load. The bottoms of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 21.0°C at 44.8% relative humidity for 20 minutes (until visibly dry). Each batch of test substance was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls. The test was conducted at room temperature (21.0°C). Near the end of the 30 second exposure time, the dried films were scraped with a cell scraper, and at the 30 second exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The MT-2 cells in multiwell culture dishes were inoculated in quadruplicate with 0.2mL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 14 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

12. MRID 490895-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Rotavirus (Strain WA), for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Shanen Conway, B.S., Study completion date, Oct. 29, 2012. Study conducted by ATS Labs. Project Number A13928.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Rotavirus, Strain WA (obtained from University of Ottawa, Ontario, Canada) with a 5% fetal bovine serum organic soil load. Testing followed Protocol Number ECO01072512.ROT (copy provided). The host cell line, MA-104 cells (Rhesus monkey kidney cells, obtained from Diagnostic Hybrids, Inc.) was maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin and 2.0 mM L-glutamine. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Test date 8/24/12, Batch 073112-CL1 dilution 357.38 g test substance plus 142.62 g diluent and Batch 080112-CL1 dilution 352.41 g test substance plus 147.59 g diluent to achieve 660 ppm available chlorine. Test date 10/04/12, Batch 073112-CL1 dilution 358.15 g test substance plus 141.85 g diluent to achieve 660 ppm available chlorine. On the day use, an aliquot of stock virus Rotavirus, Strain WA was thawed and adjusted to contain 5% FBS as the organic soil load. Test date 8/24/12, the bottoms of three 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture

and dried at 20.0°C at 50% relative humidity for 20 minutes (until visibly dry). Test date 10/04/12, the bottoms of two 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 40% relative humidity for 20 minutes (until visibly dry). On each day of testing, the carriers were sprayed at a distance of 6 to 8 inches using 3 trigger pulls and were exposed for 5 minutes at room temperature (20.0°C). Near the end of the exposure time, the dried films were individually scraped with a cell scraper, and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The MA-104 cells in multiwell culture dishes were inoculated in quadruplicate with 0.1mL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and for viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

13. MRID 490895-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Vaccina Virus, for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Shanen Conway, B.S., Study completion date, Sept. 26, 2012, Study Conducted by ATS Labs. Project Number A13927.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Vaccina virus, Strain WR (ATCC VR-119) with a 5% fetal bovine serum organic soil load. Testing followed Protocol Number ECO01072512.VAC (copy provided). The host cell line, Vero cells (ATCC CCL-81) were maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-activated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 357.38 g test substance plus 142.62 g diluent and Batch 080112-CL1 dilution 352.41 g test substance plus 147.59 g diluent to achieve 660 ppm available chlorine. On the day of use, an aliquot of stock Vaccina virus, Strain WR was thawed and adjusted to contain 5% FBS as the organic soil load. The bottoms of three separate 100 x 15 mm glass petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 50% relative humidity for 20 minutes (until visibly dry). Each batch of test substance was dispensed into one glass petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at room temperature (20.0°C). Near the end of the 5 minute exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The Vero cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable

14. MRID 490895-19 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Respiratory syncytial (RSV) virus, for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Mary J. Miller, M.T., Study completion date, Sept. 21, 2012. Study Conducted by ATS Labs. Project Number A13925.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Respiratory syncytial (RSV) virus (ATCC VR-26, Strain Long) with a 5% fetal bovine serum organic soil load. Testing followed Protocol Number ECO01072512.RSV (copy provided). The host cell line, Hep-2 (human larynx carcinoma) cells, obtained from ViroMed Labs, were maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Eagle's Minimum Essential Medium (E-MEM) supplemented with 2% (v/v) heat-activated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL Fungizone, 10 mM HEPES, 10 µg/mL vancomycin and 2 mM L-glutamine. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 357.38 g test substance plus 142.62 g diluent and Batch 080112-CL1 dilution 352.41 g test substance plus 147.59 g diluent to achieve 660 ppm available chlorine. On the day of use, an aliquot of stock RSV virus, was thawed and adjusted to contain 5% FBS as the organic soil load. The bottoms of three separate 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 50% relative humidity for 20 minutes (until visibly dry). Each batch of test substance was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at room temperature (20.0°C). Near the end of the 5 minute exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The Hep-2 cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 11 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

15. MRID 490895-20 "Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Adenovirus type 5", for product Aqualogic, Lot Numbers 051512DT-3 and 052912DT-1. Study Director Lisa Hellickson. Study conducted by Ecolab. Study completion date, Dec 18, 2012. Study ID Number 1200059.

This study was conducted using two lots of Aqualogic Lots 051512DT-3 (batch 3) and 052912DT-1 (batch 1), which were tested according to Ecolab Microbiological Services SOP Method; *Virucidal Efficacy Assay for Hard Surfaces* to determine the Virucidal efficacy against Adenovirus type 5, strain Adenoid 75 (ATCC VR-5) with a 5% fetal bovine serum organic soil load, after 5 minutes exposure at ambient temperature. Testing followed GLP Protocol Study No. 1200059 (copy provided). The two lots of test substance were diluted to 660 ppm free available chlorine in sterile laboratory purified water or Milli-Q water. Lot 051512DT-3 dilution 246.96 g test substance plus 103.05 g diluent and Lot 052912DT-1 dilution 253.75 g test substance plus 96.26 g diluent to achieve 660 ppm available chlorine. HeLa Cells (ATCC CCL-

2), from the third or greater transfer, were prepared in 24 well assay plates and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for two days prior to the test. Test medium used to maintain the cell cultures was Minimum Essential Medium, Eagle (EMEM) test medium, supplemented with 10% (v/v) heat inactivated fetal bovine serum and 50-100 IU penicillin and 50-100 µg/mL streptomycin. Several vials of stock Adenovirus type 5 were thawed and pooled on the day of the test and since 5% Fetal Bovine Serum (FBS) is present in the virus stock, no additional soil load was added. The bottom of 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried for 37 minutes in a biological safety cabinet. Each batch of use-solution was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at ambient (15°-30°C) temperature. Near the end of the 5 minute exposure time, the dried film was scraped from the surface of the dish with a cell scraper, and 0.1 mL of the virus/test mixture was pipetted into prepared sephacryl columns (0.1 mL per column – five columns used per batch) for neutralization. The columns were centrifuged for 2 minutes at 700 x g after which the supernatant was serially diluted and inoculated into assay plates seeded with the test cell culture (0.1 mL per well). Four assay wells were inoculated per dilution prepared and were incubated at 35±2°C in a humidified atmosphere at 5±2% CO_2 for 7-10 days. Controls included those for dried virus film recovery, virus stock titer confirmation, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

16. MRID 490895-21 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Human Coronavirus, for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Mary J. Miller, M.T., Study completion date, Sept. 21, 2012, Study conducted by ATS Labs. Project Number A13926.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Human Coronavirus, ATCC VR-740, Strain 229E with a 5% fetal bovine serum organic soil load. Testing followed Protocol Number ECO01072512.COR (copy provided). The host cell line, WI-38 (human lung) cells, ATCC CCL-75, were seeded into multiwell cell culture plates and maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-activated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 357.38 g test substance plus 142.62 g diluent and Batch 080112-CL1 dilution 352.41 g test substance plus 147.59 g diluent to achieve 660 ppm available chlorine. On the day of use, an aliquot of stock virus, was thawed and adjusted to contain 5% FBS as the organic soil load. The bottoms of three separate 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 50% relative humidity for 20 minutes (until visibly dry). Each batch of test substance was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at room temperature (20.0°C). Near the end of the 5 minute exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The Hep-2 cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions from the test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 11 days for the absence or presence of CPE, cytotoxicity, and for

viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

17. MRID 490895-22 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Murine Norovirus, for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Shanen Conway, B.S., Study completion date, Sept. 21, 2012. Study conducted by ATS Labs. Project Number A13932.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Murine Norovirus (MNV-1.CW1 Strain), obtained from Washington University, St. Louis, MO. Testing followed Protocol Number ECO01072512.MNV (copy provided). The host cell line, RAW 264.7 cells, a continuous mouse macrophage cell line was seeded into multiwell cell culture plates maintained and used in tissue culture at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Complete 2X MEM. The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 356.99 g test substance plus 143.01 g diluent and Batch 080112-CL1 dilution 352.78 g test substance plus 147.22 g diluent to achieve 660 ppm available chlorine. On the day of use, an aliquot of stock virus was thawed and adjusted to contain 5% FBS as the organic soil load. The bottoms of three separate 100 x 15 mm glass Petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 50% relative humidity for 20 minutes (until visibly dry). Each batch of test substance was dispensed into one glass Petri dish with a dried virus film by spraying at a distance of 6 to 8 inches using 3 trigger pulls at room temperature (20.0°C). Near the end of the 30 seconds exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The RAW 264.7 macrophage cells in multiwell culture dishes were inoculated in quadruplicate with 250 µL aliquot of the dilutions from the test and control groups. Following adsorption of 60 minutes, the inoculum was removed and an aliquot of MNV Overlay Agarose I was inoculated into each well, which were then incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 for 2 days. Following incubation, an aliquot of MNV Overlay Agarose I with neutral red stain was added and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 for 4 hours after which the cultures were microscopically observed to verify plaques or test substance cytotoxicity. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

18. MRID 490895-23 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus", for product Aqualogic, Batch 073112-CL1 and Batch 080112-CL1. Study Director Shanen Conway, B.S., Study completion date, Oct. 15, 2012. Study conducted by ATS Labs. Project Number A13931.

This study was conducted using two batches of test substance "Aqualogic", Batch 073112-CL1 and Batch 080112-CL1, which were tested against Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus (10/29/11 strain obtained from Hepadnavirus Testing Inc). The

stock virus contained 100% duck serum as the organic soil load. Testing followed Protocol Number ECO01072512.DHBV (copy provided). The host cell line, hepatocytes obtained from blood samples from Pekin hatchling ducks less than 7 days old, were seeded into sterile 12 well tissue culture labware. The cultures were maintained and used at the appropriate density and incubated at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Leibovitz L-15 medium supplemented with 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin The two batches of test substance were diluted to the lower limit of 660 ppm available chlorine in sterile deionized water. Batch 073112-CL1 dilution 356.99 g test substance plus 143.01 g diluent and Batch 080112-CL1 dilution 352.78 g test substance plus 147.22 g diluent to achieve 660 ppm available chlorine. On the day use, two aliquots of stock virus (Lot 10/29/11 pool) was thawed, combined and refrigerated until use. The stock virus cultures contained 100% duck serum as the organic soil load. The bottoms of three 100 x 15 mm glass petri dishes were inoculated with 0.2 mL of prepared virus/soil mixture and dried at 20.0°C at 50% relative humidity for 30 minutes (until visibly dry). The carriers were sprayed at a distance of 6 to 8 inches using 3 trigger pulls and were exposed for 5 minutes at room temperature (20.0°C). Near the end of the exposure time, the dried films were individually scraped with a cell scraper, and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The primary duck hepatocyte cells in cell culture dishes were inoculated in quadruplicate with 250 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 for 9 days. The test medium was aspirated from each test and control well and replaced with fresh medium as needed throughout the incubation period. On the final day of incubation, the cultures were scored microscopically for cytotoxicity and the cells were fixed with ethanol. An indirect immunofluorescence assay was then performed using a monoclonal antibody specific for the envelope protein of the DHBV.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

19. MRID 490895-24 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Herpes simplex virus type 2" for the product Aqualogic. Study director is Shanen Conway. Study conducted by ATS Labs. Study completion date – September 26, 2012. Project Number A13929.

This study was conducted against the G strain of Herpes simplex virus type 2 (ATCC VR-734) with rabbit kidney (RK) cells as the host cell line. RK cells were obtained from ViroMed Laboratories, Inc. Two lots of Aqualogic (073112-CL1 and 080112-CL1) were tested according to ATS protocol ECO01080812.HSV2 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile deionized water to yield 660 ppm available chlorine as follows:

Lot 073112-CL1; 357.38g + 142.62 g diluent = 660 ppm available chlorine
Lot 080112-CL1; 352.41g + 147.59 g diluent = 660 ppm available chlorine

The stock virus was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells and stored at <-70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot H2-64) was removed, thawed, and maintained refrigerated. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes). For each lot of test substance, one dried virus film was individually exposed for 30 seconds at room temperature (21.0°C) to the amount of spray released under

use conditions. The carriers were sprayed 3 sprays, until thoroughly wet at a distance of 6-8 inches and held covered for the exposure time. The virus films were completely covered with the test substance. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity in RK cells. RK cells in multi-well culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. All cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The host RK cells were examined microscopically and scored periodically for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability for seven days. Controls included those for plate recovery, cytotoxicity, neutralization and cell viability. Viral and Cytotoxicity titers were calculated by the Spearman Kaber method.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

20. MRID 490895-25 "Aqualogic Germicidal Spray Disinfection Efficacy Against Antibiotic Resistant Organisms" for the product Aqualogic. Study director is Laurinda Holen. Study conducted by Ecolab. Study completion date – January 11, 2013. Project Number 1200073.

This study was conducted against;
Acinetobacter baumannii (MDR ATCC BAA-1605),
Staphylococcus aureus (VISA ATCC 700788),
Staphylococcus aureus (CA-MRSA ATCC BAA-1683),
Staphylococcus aureus (MRSA ATCC 33592),
Klebsiella pneumoniae (carbapenemase producer (KPC) ATCC BAA-1705), and *Enterococcus faecalis* (VRE ATCC 51299).

Two lots (051512DT and 052912DT) of the product, Aqualogic, were tested using Ecolab Microbiological Services SOP Method MS010-21 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified water to yield 660 ppm available chlorine as follows:

Lot 51512DT-2-UD1; 499.26g + 200.74g diluent = 660 ppm available chlorine
Lot 52912DT-2-UD1; 513.12g + 186.87g diluent = 660 ppm available chlorine
Lot 51512DT-2-UD2; 359.72g + 140.26g diluent = 660 ppm available chlorine
Lot 52912DT-2-UD2; 369.39g + 130.62g diluent = 660 ppm available chlorine
Lot 51512DT-2-UD4; 501.97g + 198.05g diluent = 660 ppm available chlorine
Lot 52912DT-2-UD4; 583.92g + 116.08g diluent = 660 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. An appropriate number of tubes with 20 mL culture media were inoculated with each organism and incubated at 35 ± 2°C for 48-54 hours prior to testing. The culture media was AOAC nutrient broth for the all of the test organisms with a supplement of antibiotics added for *A. baumannii* and *S. aureus* VISA only. The test cultures were vortexed and allowed to settle for 15 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Twenty six (26) non-corrosive microscope coverslips (1"x1") were used as carriers and were inoculated with 0.01 mL of each test organism. The inoculum was spread uniformly over the carrier and placed in a sterile Petri dish matted with 2 layers of Whatman No. 2 filter paper. The Petri dishes were covered and placed in a 35 ± 2°C incubator for 30 minutes

to dry. The inoculated coverslips were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. After the 5 minute exposure period, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual 32 x 200 mm test tubes containing 20 mL of appropriate neutralizer/subculture medium using sterile forceps. Neutralization medium was Letheen broth + 0.5% sodium thiosulfate for test organisms except for *S. aureus* MRSA which was D/E broth. The subculture agar for all test organisms was Tryptone Glucose Extract. All subculture tubes and agar plates were incubated at 35 ± 2°C for 48 ± 4 hours. Following incubation, the subcultures were examined for growth. Controls included those for confirmation of antibiotic resistance by test organisms, purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population. Antibiotic susceptibility testing was performed on *Acinetobacter baumannii* (MDR ATCC BAA-1605), *Staphylococcus aureus* (CA-MRSA ATCC BAA-1683), *Staphylococcus aureus* (MRSA ATCC 33592), and *Enterococcus faecalis* (VRE ATCC 51299) using the disk diffusion method to confirm antibiotic resistance as described in Ecolab's procedures MS111-04 or MS111-05 (Antibiotic Susceptibility Tests). Multi drug resistance was verified for *Acinetobacter baumannii* (MDR ATCC BAA-1605) using 120 mcg gentamicin disks, 10 µg imipenem disks, and 30 meg ceftazidime disks. Methicillin resistance was verified for *Staphylococcus aureus* (CA-MRSA ATCC BAA-1683) and *Staphylococcus aureus* (MRSA ATCC 33592) using 1 meg oxacillin disks. Vancomycin resistance was verified for *Enterococcus faecalis* (VRE ATCC 51299) using 30 µg vancomycin disks. Antibiotic susceptibility testing was performed on *Staphylococcus aureus* (VISA ATCC 700788) using the minimum inhibitory concentration (MIC) method to confirm intermediate resistance to vancomycin. Carbapenemase production was verified for *Klebsiella pneumoniae* (carbapenemase producer (KPC) ATCC BAA-1705) by using the Modified Hodge Test.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

21. MRID 490895-26 "Aqualogic Germicidal Spray Disinfection Efficacy at 10 Minutes" for the product Aqualogic. Study director is Laurinda Holen. Study conducted by Ecolab. Study completion date – January 11, 2013. Project Number 1200077.

This study was conducted against *Enterococcus faecalis* (VRE ATCC 51299) and *Escherichia coli* O157:H7 (ATCC 43895). Two lots (051512DT and 052912DT) of the product, Aqualogic, were tested using Ecolab Microbiological Services SOP Method MS010-21 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified water to yield 660 ppm available chlorine as follows:

Lot 51512DT-3-UD; 357.78g + 142.23g diluent = 660 ppm available chlorine
Lot 52912DT-3-UD; 380.48g + 119.51g diluent = 660 ppm available chlorine
Lot 51512DT-3-UD2; 286.52g + 113.46g diluent = 660 ppm available chlorine
Lot 52912DT-3-UD2; 311.58g + 88.41g diluent = 660 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. An appropriate number of tubes with 20 mL culture media were inoculated with each organism and incubated at 35 ± 2°C for 48-54 hours prior to testing. The culture media was brain heart infusion broth for *E. coli* and brain heart infusion broth plus 100 uL 400 µg/mL vancomycin per 10 mL broth for *E. faecalis*. The test cultures were vortexed and allowed to settle for 15 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Twenty six (26) non-corrosive microscope coverslips (1"x1") were used as carriers and were inoculated with 0.01 mL of each test organism. The inoculum was spread uniformly over the carrier and placed in a sterile Petri dish matted with 2 layers of Whatman No.

2 filter paper. The Petri dishes were covered and placed in a 35 ± 2°C incubator for 30 minutes to dry. The inoculated coverslips were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. After the 10 minute exposure period, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual 32 x 200 mm test tubes containing 20 mL of appropriate neutralizer/subculture medium using sterile forceps. Neutralization medium was brain heart infusion broth + 0.5% sodium thiosulfate for *E. coli* with the addition of 0.7 g lecithin per liter and 5.0 g Tween 80 per liter for *E. faecalis*. The subculture agar for both test organisms was brain heart infusion agar. All subculture tubes and agar plates were incubated at 35 ± 2°C for 48 ± 4 hours. Following incubation, the subcultures were examined for growth. Controls included those for confirmation of antibiotic resistance by test organism, purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population. Vancomycin resistance was verified for *Enterococcus faecalis* (VRE ATCC 51299) using 30 µg vancomycin disks and the disk diffusion method.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

22. MRID 490895-27 "Aqualogic Germicidal Spray Disinfection Efficacy with *Trichophyton mentagrophytes* and *Aspergillus niger*" for the product Aqualogic. Study director is Laurinda Holen. Study conducted by Ecolab. Study completion date – January 24, 2013. Project Number 1200058.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533) and *Aspergillus niger* (ATCC 6275). Two lots (051512DT and 052912DT) of the product, Aqualogic, were tested using Ecolab Microbiological Services SOP Method MS010-21 (copy provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified water to yield 660 ppm available chlorine as follows:

Lot 51512DT-1-UD; 352.41g + 147.59g diluent = 660 ppm available chlorine
Lot 52912DT-1-UD; 359.72g + 140.29g diluent = 660 ppm available chlorine
Lot 51512DT-3-UD5; 288.12g + 111.92g diluent = 660 ppm available chlorine
Lot 52912DT-3-UD5; 346.39g + 53.59g diluent = 660 ppm available chlorine
Lot 51512DT-3-UD7; 292.56g + 107.42g diluent = 660 ppm available chlorine
Lot 52912DT-1-UD7; 368.16g + 31.86g diluent = 660 ppm available chlorine

The test organisms were transferred from Sabouraud Dextrose Agar slants to Sabouraud Dextrose agar and incubated at 26 + 2°C for 10-15 days prior to inoculating a second set of plates which were incubating at 26 ± 2°C for an additional 10-15 days. After incubation, the mycelial mats were removed from the surface of the agar by adding 5 mL of 0.85% saline to each plate. The culture suspension was transferred to a sterile glass tissue grinder and macerated with additional 0.85% saline. The suspension was then filtered through two layers of sterile cheesecloth to remove the hyphal elements. The density of the suspension was estimated by performing serial dilutions and plating on Sabouraud Dextrose agar. 0.02 mL of Triton X-100 was added per 10 mL of the test organism suspensions to facilitate spreading onto the glass slide carrier and fetal bovine serum was added to suspensions to achieve 5% organic soil load. Thirteen to twenty six (26) non-corrosive microscope coverslips (1"x1") were used as carriers and were inoculated with 0.01 mL of each test organism suspension. The inoculum was spread uniformly over the carrier and placed in a sterile Petri dish matted with 2 layers of Whatman No. 2 filter paper. The Petri dishes were covered and placed in a 35 ± 2°C incubator for 30 minutes to dry. The inoculated coverslips were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. After the 5 or 10 minute exposure period, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual 32 x 200 mm test tubes containing 20 mL of appropriate neutralizer/subculture medium using sterile forceps. The neutralization/ subculture medium for *A. niger* was

Sabouraud Dextrose Broth + 0.5% Sodium Thiosulfate and for *T. mentagrophytes* was Sabouraud Dextrose Broth + 0.7 g Lecithin/L + 5.0 g Tween 80/L. The subculture agar for both test organisms was Sabouraud Dextrose agar. All subculture tubes and agar plates were incubated at 26 ± 2°C for 3-5 days. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

23. MRID 490895-28 "Aqualogic Germicidal Spray Disinfection Efficacy" for the product Aqualogic. Study director is Laurinda Holen. Study conducted by Ecolab. Study completion date – January 24, 2013. Project Number 1200072.

This study was conducted against;

Acinetobacter baumannii (ATCC 19606),
Escherichia coli (ATCC 11229),
Klebsiella pneumoniae (ATCC 4352),
Serratia marcescens (ATCC 14756),
Shigella flexneri (ATCC 9380),
Enterobacter aerogenes (ATCC 13048),
Escherichia coli O157:H7 (ATCC 43895),
Streptococcus pyogenes (ATCC 19615),
Shigella dysenteriae (ATCC 29026),
Listeria monocytogenes (ATCC 7644), and
Enterococcus faecalis (ATCC 29212).

Two lots (051512DT and 052912DT) of the product, Aqualogic, were tested using Ecolab Microbiological Services SOP Method MS010-20 and MS010-21 (copies provided). The Aqualogic test substance was diluted to the lower certified limit in sterile laboratory purified water to yield 660 ppm available chlorine as follows:

Lot 51512DT-1-UD1; 354.57g + 145.45g diluent = 660 ppm available chlorine
Lot 52912DT-1-UD1; 362.78g + 137.23g diluent = 660 ppm available chlorine
Lot 51512DT-1-UD2; 496.01g + 203.98g diluent = 660 ppm available chlorine
Lot 52912DT-1-UD2; 508.58g + 191.40g diluent = 660 ppm available chlorine
Lot 51512DT-2-UD1; 499.79g + 200.22g diluent = 660 ppm available chlorine
Lot 52912DT-2-UD1; 503.60g + 196.39g diluent = 660 ppm available chlorine
Lot 51512DT-3-UD4; 501.97g + 198.05g diluent = 660 ppm available chlorine
Lot 52912DT-2-UD4; 583.92g + 116.08g diluent = 660 ppm available chlorine
Lot 51512DT-3-UD7; 292.56g + 107.42g diluent = 660 ppm available chlorine
Lot 52912DT-1-UD7; 368.16g + 31.86g diluent = 660 ppm available chlorine

As per protocol, the test organisms were prepared by inoculation from stock cultures and transferred greater than 3 times but less than or equal to 15 times in a suitable growth medium prior to being used in the test. An appropriate number of tubes with 20 mL culture media were inoculated with each organism and incubated at 35 ± 2°C for 48-54 hours prior to testing with the exception of *Serratia marcescens* which was incubated at 26 ± 2°C for 48-54 hours and *Enterobacter aerogenes* which was incubated at 30 ± 2°C for 48-54 hours. The culture media was AOAC nutrient broth for the all of the test organisms except for *Escherichia coli* O157:H7, *Streptococcus pyogenes*, *Listeria monocytogenes*, and *Enterococcus faecalis* which were grown in brain heart infusion broth. The test cultures were vortexed and allowed to settle for 15 minutes. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Thirteen to twenty six (26) non-corrosive microscope coverslips (1"x1") were used as carriers and were inoculated with 0.01 mL of each test organism. The inoculum was spread uniformly over the carrier and placed in a sterile Petri dish matted with 2 layers of Whatman No. 2 filter paper. The Petri dishes were covered and placed in a 35 ± 2°C incubator for 30-33 minutes to

dry. The inoculated coverslips were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. After the 5 minute exposure period, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual 32 x 200 mm test tubes containing 20 mL of appropriate neutralizer/subculture medium using sterile forceps. Neutralization medium was Letheen broth + 0.5% sodium thiosulfate for test organisms except for; *Escherichia coli* O157:H7 which was brain heart infusion broth + 0.5% Sodium Thiosulfate; *Streptococcus pyogenes*, *Listeria monocytogenes*, and *Enterococcus faecalis* was D/E broth. The subculture agar for all test organisms was Tryptone Glucose Extract except for *Escherichia coli* O157:H7, *Streptococcus pyogenes*, *Listeria monocytogenes*, and *Enterococcus faecalis* which was brain heart infusion agar. All subculture tubes and agar plates were incubated at 35 ± 2°C for 48 ± 4 hours with the exception of *Serratia marcescens* which was incubated at 26 ± 2°C for 48 ± 4 hours and *Enterobacter aerogenes* which was incubated at 30 ± 2°C for 48 ± 4 hours. Following incubation, the subcultures were examined for growth. Controls included those for purity, sterility, viability, neutralization confirmation, bacteriostasis, and carrier population.
Note: Protocol deviations/amendments reported in this study were reviewed and found to be acceptable.

V. RESULTS

Table 1. UDM Test Results 5-Minute Exposure Time at 660 ppm Chlorine

MRID Number	Organism	No. Carriers Exhibiting Growth/ Total No. Carriers Tested			Average Carrier Population (CFU/carrier)
		Lot 51512DT-1	Lot 52912DT-1	Lot 50112DT-1*	
490895-12	*Staphylococcus aureus* (ATCC 6538)	1/60	0/60	0/60	3.7×10^6
	Pseudomonas aeruginosa (ATCC 15442)	0/60	0/60	0/60	4.5×10^5
	Salmonella enterica (ATCC 10708)	1/60	0/60	1/60	5.0×10^5

*≥60 days old

MRID Number	Organism	Lot	No. Exhibiting Growth/Total No. Tested	Carrier Population (CFU/carrier)
5-Minute Exposure Time at 660 ppm Chlorine				
490895-25	*Acinetobacter baumannii* (MDR ATCC BAA-1605)	51512DT-2-UD1	0/10	4.6×10^4
		52912DT-2-UD1	0/10	
	Staphylococcus aureus (CA-MRSA ATCC BAA-1683)	51512DT-2-UD1	0/10	3.8×10^5
		52912DT-2-UD4	0/10	
	Klebsiella pneumoniae (KPC) (ATCC BAA-1705)	51512DT-2-UD2	0/10	1.2×10^5
		52912DT-2-UD2	0/10	
	Staphylococcus aureus (VISA ATCC 700788)	51512DT-2-UD2	0/10	8.3×10^5
		52912DT-2-UD2	0/10	
	Staphylococcus aureus (MRSA ATCC 33592)	51512DT-3-UD4	0/10	1.1×10^6
		52912DT-2-UD4	0/10	

MRID Number	Organism	Lot	No. Exhibiting Growth/Total No. Tested	Carrier Population (CFU/carrier)
5-Minute Exposure Time at 660 ppm Chlorine				
490895-28	*Acinetobacter baumannii* (ATCC 19606)	51512DT-1-UD1	0/10	1.0×10^6
		52912DT-1-UD1	0/10	
	Escherichia coli (ATCC 11229)	51512DT-1-UD1	0/10	4.6×10^4
		52912DT-2-UD1	0/10	
	Serratia marcescens (ATCC 14756)	51512DT-1-UD1	0/10	4.8×10^6
		52912DT-1-UD1	0/10	
	Klebsiella pneumoniae (ATCC 4352)	51512DT-1-UD1	0/10	2.9×10^5
		52912DT-1-UD1	0/10	
	Escherichia coli O157:H7 (ATCC 43895)	51512DT-1-UD2	3/10	3.0×10^6
		52912DT-1-UD2	0/10	
	Enterobacter aerogenes (ATCC 13048)	51512DT-1-UD2	0/10	7.7×10^5
		52912DT-2-UD4	0/10	
	Shigella flexneri (ATCC 9380)	51512DT-2-UD1	0/10	3.0×10^4
		52912DT-2-UD1	0/10	
	Shigella dysenteriae (ATCC 29026)	51512DT-2-UD1	0/10	3.2×10^6
		52912DT-2-UD1	0/10	
	Listeria monocytogenes (ATCC 7644)	51512DT-3-UD4	0/10	3.1×10^5
		52912DT-2-UD4	0/10	
	Enterococcus faecalis (ATCC 29212)	51512DT-3-UD4	0/10	8.8×10^5
		52912DT-2-UD4	0/10	
	Streptococcus pyogenes (ATCC 19615)	51512DT-3-UD7	0/10	5.0×10^4
		52912DT-1-UD7	0/10	

MRID Number	Organism	Lot	No. Exhibiting Growth/Total No. Tested	Carrier Population (CFU/carrier)
10-Minute Exposure Time at 660 ppm Chlorine				
490895-26	*Escherichia coli* O157:H7 (ATCC 43895)	51512DT-3-UD	0/10	2.4×10^6
		52912DT-3-UD	0/10	
	Enterococcus faecalis (VRE ATCC 51299)	51512DT-3-UD2	0/10	2.1×10^6
		52912DT-3-UD2	0/10	

MRID Number	Organism	Lot	No. Exhibiting Growth/Total No. Tested	Carrier Population (CFU/carrier)
5-Minute Exposure Time at 660 ppm Chlorine				
490895-27	*Aspergillus niger* (ATCC 6275)	51512DT-1-UD	3/10	2.2×10^6
		52912DT-1-UD	0/10	
	Trichophyton mentagrophytes (ATCC 9533)	51512DT-3-UD5	2/10	2.8×10^5
		52912DT-3-UD5	0/10	
10-Minute Exposure Time at 660 ppm Chlorine				
490895-27	*Aspergillus niger* (ATCC 6275)	51512DT-3-UD5	0/10	1.3×10^4
	Trichophyton mentagrophytes (ATCC 9533)	51512DT-3-UD7	0/10	1.9×10^5
		52912DT-1-UD7	0/10	

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/mL		
3-Minute Exposure Time at 260 ppm Chlorine					
490895-13	*Enterobacter aerogenes* (ATCC 13048)	51512DT-1 52912DT-2 50112DT-1*	$<2.5 \times 10^1$ $<2.5 \times 10^1$ $<2.5 \times 10^1$	1.4×10^9 9.9×10^8 5.3×10^8	>99.9 >99.9 >99.9
4-Minute Exposure Time at 260 ppm Chlorine					
490895-13	*Staphylococcus aureus* (ATCC 6538)	51512DT-2 52912DT-2 50112DT-1*	$<6.3 \times 10^2$ $<1.8 \times 10^3$ $<1.6 \times 10^2$	3.5×10^8 2.8×10^8 1.6×10^8	>99.9 >99.9 >99.9

*≥60 Days old

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/mL		
1-Minute Exposure Time at 660 ppm Chlorine					
490895-14	*Enterobacter aerogenes* (ATCC 13048)	51512DT-1 52912DT-2 50112DT-1*	$<2.5 \times 10^1$ $<2.5 \times 10^1$ $<2.5 \times 10^1$	1.4×10^9 9.9×10^8 5.3×10^8	>99.9 >99.9 >99.9
	Staphylococcus aureus (ATCC 6538)	51512DT-1 52912DT-2 50112DT-1*	$<3.6 \times 10^2$ $<8.1 \times 10^2$ $<6.1 \times 10^1$	2.6×10^8 2.8×10^8 1.6×10^8	>99.9 >99.9 >99.9

*≥60 Days old

MRID Number	Organism	Results @ 30 Second Contact Time 660 ppm Chlorine			Dried Virus Count
			Lot # 073112-CL1	Lot # 080112-CL1	
490895-16	HIV type 1 (strain HTLV-III_B)	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.50}$ $TCID_{50}$/0.2 mL
		$TCID_{50}$/0.2 mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
490895-22	Murine Norovirus (MNV-1.CW1 Strain)	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.25}$ PFU_{50}/250 µL
		PFU_{50}/250 µL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
490895-24	Herpes Simplex Virus Type 2 (HSV2) (ATCC VR-734)	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

MRID Number	Organism	Results @ 30 Second Contact Time 660 ppm Chlorine			Dried Virus Count
			Lot # 051512DT-2	Lot # 052912DT-2	
490895-07	Rhinovirus Type 37 (strain 151-1 ATCC VR-1147)	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{4.50}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
490895-10	Herpes Simplex Type 1 (strain F (1) ATCC VR-733)	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{4.50}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	

MRID Number	Organism	Results @ 30 Second Contact Time 660 ppm Chlorine*			Dried Virus Count**
			Lot # 051512DT-2	Lot # 052912DT-1	
490895-08	Norovirus [Feline Calcivirus (strain F-9 ATCC VR-782) as surrogate]	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{6.25}$
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1 mL

*Both Lots had two replicates. Lot 0515112DT-2 was originally tested as Lot 051512DT-3, but one replicate showed CPE in an abnormal pattern. Testing on this lot was repeated twice to verity that CPE was due to aerosolizaton. The final assessment was complete inactivation as shown above.
**Six different dried virus tests were conducted and all passed. Only one is presented here.

MRID Number	Organism	Results @30 Second Contact Time 660 ppm Chlorine			Dried Virus Count
			Lot # 051512DT-2	Lot # 052912DT-3	
490895-15	Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736)	10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.25}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL

MRID Number	Organism	Results @30 Second Contact Time 260 ppm Chlorine			Dried Virus Count
			Replicate 1 Lot # 051512DT-2	Replicate 1 Lot # 052912DT-2	
490895-09	Norovirus [Feline Calcivirus (strain F-9 ATCC VR-782) as surrogate]	10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.25}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL
			Replicate 2 Lot # 051512DT-2	Replicate 2 Lot # 052912DT-2	
		10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL
490895-06	Rhinovirus Type 37 (strain 151-1 ATCC VR-1147)	10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.25}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL

MRID Number	Organism	Results @30 Second Contact Time 260 ppm Chlorine			Dried Virus Count
			Lot # 051512DT-2	Lot # 052912DT-3	
490895-11	Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736)	10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.38}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL

MRID Number	Organism	Results @5 Minute Contact Time 660 ppm Chlorine			Dried Virus Count
			Lot # 051512DT-3	Lot # 052912DT-1	
490895-20	Adenovirus type 5, strain Adenoid 75 (ATCC VR-5)	10^{-1} to 10^{-5} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1mL

MRID Number	Organism	Results @ 5 Minute Contact Time 660 ppm Chlorine			Dried Virus Count
			Lot # 073112-CL1	Lot # 080112-CL1	
490895-17	Rotavirus, Strain WA	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{5.50}$ $10^{6.25**}$
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50*}$	$\leq 10^{0.50}$	$TCID_{50}$/0.1 mL
490895-18	Vaccina virus, Strain WR (ATCC VR-119)	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{7.50}$
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	$TCID_{50}$/0.1 mL
490895-19	Respiratory syncytial (RSV) virus (ATCC VR-26, Strain Long)	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{5.00}$
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	$TCID_{50}$/0.1 mL
490895-21	Human Coronavirus, ATCC VR-740, Strain 229E	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	$TCID_{50}$/0.1 mL
490895-23	Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$TCID_{50}$/0.250 mL $10^{5.75}$
		$TCID_{50}$/0.250 mL	Replicate 1 $\leq 10^{0.50}$	Replicate 1 $\leq 10^{0.50}$	
			Replicate 2 $\leq 10^{0.50}$	Replicate 2 $\leq 10^{0.50}$	$TCID_{50}$/0.250 mL $10^{6.00}$

*Tested twice (8/24/12 and 10/04/12)
**Result for second test for Lot 073112-CL1

VI. CONCLUSIONS

1.) The submitted efficacy data **support** the use of Hydris at a dilution of 660 ppm chlorine in sterile deionized water as a disinfectant against the following organisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Staphylococcus aureus (ATCC 6538)	MRID 490895-12
Pseudomonas aeruginosa (ATCC 15442)	MRID 490895-12
Salmonella enterica (ATCC 10708)	MRID 490895-12
Acinetobacter baumannii (MDR ATCC BAA-1605)	MRID 490895-25
Staphylococcus aureus (VISA ATCC 700788)	MRID 490895-25
Staphylococcus aureus (CA-MRSA ATCC BAA-1683)	MRID 490895-25
Staphylococcus aureus (MRSA ATCC 33592)	MRID 490895-25
Klebsiella pneumoniae (KPC) ATCC BAA-1705)	MRID 490895-25
Acinetobacter baumannii (ATCC 19606)	MRID 490895-28
Escherichia coli (ATCC 11229)	MRID 490895-28
Klebsiella pneumoniae (ATCC 4352)	MRID 490895-28
Serratia marcescens (ATCC 14756)	MRID 490895-28

Shigella flexneri (ATCC 9380)	MRID 490895-28
Enterobacter aerogenes (ATCC 13048)	MRID 490895-28
Streptococcus pyogenes (ATCC 19615)	MRID 490895-28
Shigella dysenteriae (ATCC 29026)	MRID 490895-28
Listeria monocytogenes (ATCC 7644)	MRID 490895-28
Enterococcus faecalis (ATCC 29212)	MRID 490895-28

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic resistance was demonstrated for resistant test organisms in confirmation tests. Neutralization confirmation testing showed positive growth of the microorganisms.

2.) The submitted efficacy data **support** the use of Hydris at a dilution of 660 ppm chlorine in sterile deionized water as a disinfectant against the following organisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time:

Escherichia coli O157:H7 (ATCC 43895)	MRID 490895-26
Enterococcus faecalis (VRE ATCC 51299)	MRID 490895-26
Aspergillus niger (ATCC 6275)	MRID 490895-27
Trichophyton mentagrophytes (ATCC 9533)	MRID 490895-27

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Neutralization confirmation testing showed positive growth of the microorganisms. Antibiotic resistance was demonstrated for *Enterococcus faecalis* (VRE) in confirmation tests.

3.) The submitted efficacy data **support** the use of Hydris at a dilution of 260 ppm chlorine in 250 ppm sterile hard water as a sanitizer for inanimate, non-food contact surfaces against the following bacteria in the presence of 5% organic soil load for 3-minute contact at room temperature for *Enterobacter aerogenes* (ATCC 13048) and 4 minute contact at *Staphylococcus aureus* (ATCC 6538).

Enterobacter aerogenes (ATCC 13048)	MRID 490895-13
Staphylococcus aureus (ATCC 6538)	MRID 490895-13

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

4.) The submitted efficacy data **support** the use of Hydris at a dilution of 660 ppm chlorine in sterile deionized water as a sanitizer for inanimate, non-food contact surfaces against the following bacteria in the presence of 5% organic soil load for *a* 1-minute contact at room temperature.

Enterobacter aerogenes (ATCC 13048)	MRID 490895-14
Staphylococcus aureus (ATCC 6538)	MRID 490895-14

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity

controls were reported as pure. Sterility controls did not show growth.

5.) The submitted efficacy data **support** the use of Hydris at a dilution of 260 ppm chlorine as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for and sterile 400 ppm hard water for a 30 second contact time:

Rhinovirus Type 37 -260 ppm (strain 151-1 ATCC VR-1147)	MRID 490895-06
Feline Calcivirus (strain F-9 ATCC VR-782)	MRID 490895-09
Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736)	MRID 490895-11

Recoverable virus titers of at least 10^4 were achieved. No cytotoxicity was observed. Complete inactivation (no growth) was indicated in all dilutions tested.

6.) The submitted efficacy data **support** the use of Hydris at a dilution of 660 ppm chlorine as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 30 second contact time:

Rhinovirus Type 37 (strain 151-1 ATCC VR-1147)	MRID 490895-07
Norovirus [Feline Calcivirus (strain F-9 ATCC VR-782) as surrogate]	MRID 490895-08
Herpes Simplex Type 1 (strain F (1) ATCC VR-733)	MRID 490895-10
Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736)	MRID 490895-15
HIV type 1 (strain HTLV-III_B)	MRID 490895-16
Murine Norovirus (MNV-1.CW1 Strain)	MRID 490895-22
Herpes Simplex Virus Type 2 (HSV2) (ATCC VR-734)	MRID 490895-24

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was only observed with HIV type 1 (strain HTLV-III_B) and only at a dilution of 10^{-1}. Complete inactivation (no growth) was indicated in all other dilutions tested.

7.) The submitted efficacy data **support** the use of Hydris at a dilution of 660 ppm chlorine as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5 minute contact time:

Rotavirus, Strain WA	MRID 490895-17
Vaccina virus, Strain WR (ATCC VR-119)	MRID 490895-18
Respiratory syncytial (RSV) virus (ATCC VR-26, Strain Long)	MRID 490895-19
Adenovirus type 5, strain Adenoid 75 (ATCC VR-5)	MRID 490895-20
Human Coronavirus, ATCC VR-740, Strain 229E	MRID 490895-21
Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus	MRID 490895-23

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

VII. RECOMMENDATIONS

1. The label claims that Hydris™ (825 ppm FAC) is an effective disinfectant against the following organisms on hard, non-porous surfaces for a 5-minute contact time:

Acinetobacter baumannii (MDR ATCC BAA-1605),
Staphylococcus aureus (VISA ATCC 700788),
Staphylococcus aureus (CA-MRSA ATCC BAA-1683),
Staphylococcus aureus (MRSA ATCC 33592),
Klebsiella pneumoniae (carbapenemase producer (KPC) ATCC BAA-1705),
Acinetobacter baumannii (ATCC 19606),
Escherichia coli (ATCC 11229),
Klebsiella pneumoniae (ATCC 4352),
Serratia marcescens (ATCC 14756),
Shigella flexneri (ATCC 9380),
Enterobacter aerogenes (ATCC 13048),
Streptococcus pyogenes (ATCC 19615),
Shigella dysenteriae (ATCC 29026),
Listeria monocytogenes (ATCC 7644)
Enterococcus faecalis (ATCC 29212),
Staphylococcus aureus (ATCC 6538),
Pseudomonas aeruginosa (ATCC 15442), and
Salmonella enterica (ATCC 10708).

These claims are acceptable as they are supported by the submitted data.

2. The label claims that Hydris™ (825 ppm FAC) is an effective disinfectant against the following organisms on hard, non-porous surfaces for a 10-minute contact time:

Escherichia coli O157:H7 (ATCC 43895)
Enterococcus faecalis (VRE ATCC 51299)
Aspergillus niger (ATCC 6275)
Trichophyton mentagrophytes (ATCC 9533)

These claims are acceptable as they are supported by the submitted data.

3. The label claims that Hydris™ (260 ppm FAC) in 250 ppm hard water is an effective non-food contact sanitizer against the following organisms on hard, non-porous surfaces for a 4-minute contact time:

Staphylococcus aureus (ATCC 6538)
Enterobacter aerogenes (ATCC 13048)

These claims are acceptable as they are supported by the submitted data.

4. The label claims that Hydris™ (825 ppm FAC) is an effective non-food contact sanitizer against the following organisms on hard, non-porous surfaces for a 1-minute contact time:

Staphylococcus aureus (ATCC 6538)
Enterobacter aerogenes (ATCC 13048)

These claims are acceptable as they are supported by the submitted data.

5. The label claims that Hydris™ (260 ppm FAC) is an effective virucide against the following organisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 400 ppm hard water for a 30-second contact time:

Rhinovirus Type 37 (strain 151-1 ATCC VR-1147)
Norovirus [Feline Calcivirus (strain F-9 ATCC VR-782) as surrogate]
Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009
ATCC VR-1736)

These claims are acceptable as they are supported by the submitted data.

6. The label claims that Hydris™ (825 ppm FAC) is an effective virucide against the following organisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 30-second contact time:

Rhinovirus Type 37 (strain 151-1 ATCC VR-1147)
Norovirus [Feline Calcivirus (strain F-9 ATCC VR-782) as surrogate]
Herpes Simplex Type 1 (strain F (1) ATCC VR-733)
Influenza A Virus (H1N1 strain A/Virginia/ATCC1/2009 ATCC VR-1736)
HIV type 1 (strain HTLV-III_B)
Murine Norovirus (MNV-1.CW1 Strain)
Herpes Simplex Virus Type 2 (HSV2) (ATCC VR-734)

These claims are acceptable as they are supported by the submitted data.

7. The label claims that Hydris™ (825 ppm FAC) is an effective virucide against the following organisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5 minute contact time:

Rotavirus, Strain WA
Vaccina virus, Strain WR (ATCC VR-119)
Respiratory syncytial (RSV) virus (ATCC VR-26, Strain Long)
Adenovirus type 5, strain Adenoid 75 (ATCC VR-5)
Human Coronavirus, ATCC VR-740, Strain 229E
Duck Hepatitis B Virus as a Surrogate Virus for
Human Hepatitis B Virus

These claims are acceptable as they are supported by the submitted data.

LABEL RECOMMENDATIONS

- The label should state that the ready to use product is 825 ppm FAC and provide dilution instructions where the label states to use a lower FAC for sanitizing and some virucide uses.
- The statement "This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 influenza A virus" is too broad and needs modification as not all strains have been tested.
- Statements such as "kills 99.9% of bacteria" and "germicidal" need to refer to the labeled organisms.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

July 25, 2013

DP BARCODE:	412109
MRID:	49089500, 49089501, 49089502, 449089503, 49089504, 49089505,
SUBJECT:	Hydris
REG. NO.:	1677-EUR
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
014703	7681-52-9	Sodium hypochlorite

TEST LAB:	Ecolab
SUBMITTER:	Theodore D. Head
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	July 25, 2013
COMMENT:	This product is for non-food use.

L. T. U-E.
7/29/2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

July 25, 2013

MEMORANDUM

SUBJECT:	Product Chemistry Review for EPA Reg. 1677-EUR Product Name: Hydris DP Barcode: 412109
CODE:	A540; New Product; Non-Fast Track;
DATE DUE:	September 17, 2013
FROM:	Lynette T. Umez-Eronini, Chemist Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	Demson Fuller PM #32/Nathan Mottl Regulatory Management Branch II Antimicrobials Division (7510P)
Applicant:	Ecolab Inc.

Lynette T. Umez-Eronini 7/25/2013

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium Hypochlorite	0.0866
Other Ingredient(s):	99.9134
Total:	100.00

BACKGROUND:

On behalf of the registrant, Ecolab Inc., the consultant, Theodore Head, has submitted an application for registration of a non-integrated end-use product, called "Hydris. The product is a disinfectant, sanitizer, virucide, fungicide, mildewcide, bactericide, cleaner, and deodorizer. This product is used on hard non-food contact surfaces and hard, non-porous surfaces.

The original data package included:

1. Application for Pesticide, dated March 25, 2013
2. Basic Confidential Statement of Formula (CSF), dated March 25, 2013.
3. Draft label, pin-punched March 27, 2013.
4. Certificate with Respect to Citations of Data, dated March 20, 2013.
5. Formulator's Exemption Statement, dated March 25, 2013
6. Data Matrix, 3 pages, dated March 25, 2013.
7. MRID 49089500: Transmittal Document/Letter from Registrant to EPA, dated March 25, 2013 and Ecolab, Inc. (2013) Submission of Product Chemistry, Efficacy and Toxicity Data in Support of the Application for Registration of Hydris. Transmittal of 34 Studies. Transmittal of 34 Studies.
8. MRID 49089501: Hiraoka, B. (2012) SDIC-D Dihydrate Product: Product Identity and Composition and Analysis and Certification of Product Ingredients ("Series 61 and 62 Data"). Unpublished study prepared by Nankai Chemical Co. 35p.
9. MRID 49089502: Davis, B. (2013) Chemical Characterization (Disinfectant - Ambient): AquaLogic. Project Number: 1200040. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 64p.
10. MRID 49089503: Davis, B. (2012) AquaLogic: Storage Stability (Disinfectant - Ambient). Project Number: 1200017. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 29p.
11. MRID 49089504: Davis, B. (2012) AquaLogic: Storage Stability (Sanitizer Cleaner & Glass Cleaner - Ambient): Sanitizer Spray Bottle - Ambient Storage. Project Number: 1200018. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 35p.
12. MRID 49089505: Davis, B. (2013) AquaLogic: Storage Stability (Disinfectant - Refrigerated). Project Number: 1200019. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 38p.
13. MRID 49089506: Hellickson, L. (2012) Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus Type 37-260 ppm. Project Number: 1200063. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 69p.
14. Data matrix, 3 pages, March 14, 2013.

A revised data package was reviewed and included:

1. Basic CSF, July 24, 2013.

FINDINGS:

1. Basic CSF, dated March 25, 2013 is obsolete.
2. Basic CSF, dated July 24, 2013 supersedes all previous Basic CSFs.
3. Basic CSF, dated July 24, 2013 and the label have the same nominal concentration for the active ingredient.
4. Support for wider certified limits to accommodate the extended shelf life of the product is acceptable.
5. All ingredients in this formulation are approved for use in pesticide formulations.
6. Group A product chemistry data requirements applicable to end-use products have been met (see MRID# 49809501 and Table A below).
7. Group B product chemistry data requirements applicable to end-use products have been met (see MRID# 49809501, 49809502, 49809503, 49809504, and 49809505 and Table B).

CONCLUSION:

The Basic CSF, dated July 24, 2013 is acceptable. Group A and Group B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Sodium hypochlorite	0.0866	0.1083	0.0693

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49809501
830.1600 Description of Materials	A	49809501
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	49809501
830.1670 Formation of Impurities[4]	NA	
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A	49809501
830.1800 Enforcement Analytical Method[7]	A	49809501
830.1900 Submittal of Samples	A	49809501

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A		49089501
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Product is a known to be an oxidant.	49089501
830.6315 Flammability/ Flame Extension	A	Product does not contain any flammable ingredients.	49089501
830.6316 Explodability	A	Product does not contain any explodable ingredients.	49089501
830.6317 Storage Stability	A		49089502 49089503 49089504 49089505
830.6319 Miscibility[1]	A	Product is not intended for use with oil or a non-polar solvent.	49089501
830.6320 Corrosion Characteristics	A		49089502 49089503 49089504 49089505
830.6321 Dielectric Breakdown Voltage	A	Product is a conducting liquid that will not be used around electrical equipment.	49089501
830.7000 pH[2]	A	Reported 5 values ranging from pH of 9.67 – 10.60	49089501
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	Reported 5 values ranging from 2.40 - 3.00 cps.	49089501
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	Reported 5 values for specific gravity ranging from 1.0000 – 1.0003.	49089501

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7370 Dissociation Constants in Water	A		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

ECOLAB®

Theodore Head
DIRECTOR GLOBAL PRODUCT REGISTRATION

T 651 795 6814
F 651 225 3122

370 WABASHA STREET NORTH
ST. PAUL, MN 55102-1390
Ted.Head@ecolab.com

March 25, 2013

Document Processing Desk (E-SUB)
Office of Pesticide Programs (7502P)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Monisha Harris, PM-32

Re: Hydris
EPA Reg. No. [1677-pending]

Dear Monisha:

Ecolab Inc. is requesting a new pesticide registration for the above-named product. Enclosed you will find all the required EPA forms, data and certification of PRIA Fee Payment.

We believe that this submission falls into PRIA Category A532 New End Use Product that uses registered source of the active ingredient with a 5 month review and $4,631 PRIA Fee.

A brief background on the entirety of this project will help facilitate the Agency in its review. On February 1, 2013 the Agency received a registration submission from Ecolab called Hydris Mineral Activator Tablet (OPP Decision Number D-474712, EPA Reg. No. 1677-EUN).

The Hydris Mineral Activator Tablet will be used with a pesticide device that has a three chamber electrolytic cell to generate a sodium hypochlorite solution to be used onsite with no sale or distribution. Ecolab had meet with Dennis Edwards on June 7, 2012 to discuss regulatory pathway and we were advised that if distribution and sale of the salt tablet was intended then registration of the salt tablet (Hydris Mineral Activator Tablet) would be required as an MUP. We also had guidance from Mark Hartman on October 21, 2011 that registration of the bleach solution output from the EPA device would also be acceptable and that other registrants had previously pursued this pathway. This submission addresses the End Use Product Hydris (output from device) that we had indicated would follow the MUP submission the Agency received in February. From a diagram perspective it looks like the following.

EPA Registered MUP (1677-EUN submitted 2/1/13) → Pesticide Device → EPA Registered EUP (This Submission)

I would also like to point out that many of study names for prdoduct chemistry, efficacy and toxicity were conducted on a products called Aqualogic or XY-12.

Aqualogic is identical to Hydris. Hydris is the commercial name from our marketing group while Aqualogic was the project name from the R&D team.

XY-12 / Ultra San (EPA Reg. No. 1677-52) is the same formula as Hydris just at a higher concentration. Accordingly the toxicity data at the higher concentration is being used to bridge down to the Hydris submission with a lower concentration.

I trust that this additional information will be useful in the review of this application and the End Use Product submission to follow in March. Please do not hesitate to contact me if you require any additional information or have any questions about this submission.

Sincerely,

Theodore D. Head
Director Global Product Registration
Law & Regulatory Affairs

TRANSMITTAL DOCUMENT

Name and Address	Ecolab Inc 370 Wabasha Street North St. Paul MN 55102
Regulatory action in support of Which this package is submitted:	Hydris
EPA Reg. No./File Symbol:	1677-[pending]
Transmittal Date:	03-25-13

Volume No.	Citation	MRID Number
1. Product Chemistry		
	Davis (2012) Aqualogic Chemical Characterization OPPTS Guidelines 830.1550 - 830.7950 Ecolab Study No. 1200040 64 pages total .	49089501
	Davis (2012) Aqualogic Day Tank Ambient Chemical Characterization OPPTS Guidelines 830.6317, 6320 Ecolab Study No. 1200020 22 pages total .	49089502
	Davis (2012) Aqualogic Ambient (Disinfectant) Chemical Characterization OPPTS Guidelines 830.6317, 6320 Ecolab Study No. 1200017 29 pages total .	49089503
	Davis (2012) Aqualogic 715 ppm Ambient (Sanitizer) Chemical Characterization OPPTS Guidelines 830.6317, 6320 Ecolab Study No. 1200018 35 pages total .	49089504
	Davis (2012) Aqualogic Refrigerated (Disinfectant) Chemical Characterization OPPTS Guidelines 830.6317, 6320 Ecolab Study No. 1200019 38 pages total .	49089505

2. Efficacy Studies

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Rinovirus Type 37 260 ppm
Ecolab Inc, Study No. 1200063. 69 pages total. **49089506**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Rinovirus Type 37 660 ppm
Ecolab Inc, Study No. 1200062. 59 pages total. **49089507**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Norovirus 660 ppm
Ecolab Inc, Study No. 1200066. 68 pages total. **49089508**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Norovirus 260 ppm
Ecolab Inc, Study No. 1200067. 73 pages total. **49089509**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Herpes Simplex Type 1
Ecolab Inc, Study No. 1200064. 59 pages total. **49089510**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Influenza A Virus -260 ppm
Ecolab Inc, Study No. 1200061. 63 pages total. **49089511**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 GSP Hospital Disinfection
Ecolab Inc, Study No. 1200052. 67 pages total. **49089512**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Non-Food Contact Sanitizing 4 mins
Ecolab Inc, Study No. 1200054. 70 pages total. **49089513**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Non-Food Contact Sanitizing 1 min
Ecolab Inc, Study No. 1200053. 72 pages total. **49089514**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Influenza A Virus 660 ppm
Ecolab Inc, Study No. 1200060. 52 pages total. **49089515**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 HIV Type 1
Ecolab Inc, Study No. 1200074CL6. 29 pages total. **49089516**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Rotavirus
Ecolab Inc, Study No. 1200074CL2. 36 pages total. **49089517**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Vaccinia virus
Ecolab Inc, Study No. 1200074CL1. 29 pages total. **49089518**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 RSV
Ecolab Inc, Study No. 1200074CL3. 28 pages total. **49089519**

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Adenovirus Type 5
Ecolab Inc, Study No. 1200059. 57 pages total. **49089520**

Miller (2012) Aqualogic
OCSPP Guideline 810.2200 Human Coronavirus
Ecolab Inc, Study No. 1200074CL5. 28 pages total. **49089521**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 MNV-1
Ecolab Inc, Study No. 1200074CL4. 29 pages total. **49089522**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Hepatitis B Virus
Ecolab Inc, Study No. 1200074CL7. 31 pages total. **49089523**

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Herpes Simplex Type 2
Ecolab Inc, Study No. 1200074CL8. 29 pages total. **49089524**

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 Antibiotic Resistant Organisims
Ecolab Inc, Study No. 1200073. 92 pages total. **49089525**

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 GSP 10 minutes
Ecolab Inc, Study No. 1200077. 59 pages total. **49089526**

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 T. mentagrophytes, A. niger
Ecolab Inc, Study No. 1200058. 75 pages total. **49089527**

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 GSP
Ecolab Inc, Study No. 1200072. 87 pages total. **49089528**

3. Toxicity Studies

Smith (2013) XY-12 Acute Inhalation Toxicity
Health Effects Test Guidelines –OPPTS 870.1300
Ecolab Inc, Study No. 1200041CL4. 100 pages total. **49089529**

Vasquez (2013) XY-12 Contact Sensitization
Health Effects Test Guidelines –OPPTS 870.2600
Ecolab Inc, Study No. 1200041CL3. 59 pages total. **49089530**

Vasquez (2013) XY-12 Acute Dermal Toxicity
Health Effects Test Guidelines –OPPTS 870.1200
Ecolab Inc, Study No. 1200041CL2. 56 pages total. **49089531**

Vasquez (2013) XY-12 Acute Oral Toxicity
Health Effects Test Guidelines –OPPTS 870.1100
Ecolab Inc, Study No. 1200041CL1. 49 pages total. **49089532**

Vasquez (2012) XY-12 Primary Eye Irritation Use Dilution
Health Effects Test Guidelines –OPPTS 870.2400
Ecolab Inc, Study No. 1100052CL2. 56 pages total. **49089533**

Vasquez (2012) XY-12 Primary Dermal Irritation Use Dilution
Health Effects Test Guidelines –OPPTS 870.2500
Ecolab Inc, Study No. 1100052CL1. 53 pages total. **49089534**

Company Official:	Theodore D. Head, Director Global Registrations	
Company Name:	Ecolab Inc	
Company Contact:	Theodore D. Head	Phone: (651) 795-6814

NEW APPLICATIONS

DATE: 03/27/13

FILE NUMBER: 1677-EUR

FEP (OPPIN ENTRY) [illegible] MAR 27 2013
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

↘ ASSIGN TO PM JJ (NO DATA)

____ JACKET TO SHELF (DATA)

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-27-13

Experts In-Processing Signature: B. R Date 3-29-13 Fee Paid: Yes ✓

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number: 1677-EUR	EPA Receipt Date: 3-27-13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

— Studies associated with this submission initially had some deficiencies. Study # 29 (MRID 490895-29) was missing the sign of submitter and date in pg. 2.. pg. 3 was missing the sign, and date of study sponsor and submitter. Study # 30 (MRID 490895-30) was missing the sign and date of sponsor in pg. 3. Study# 31 (MRID 490895-31) was missing the sign and date of study sponsor in pg. 3. Registrant upon contact regarding deficiencies sent corrections on 04/10/13.

— contacts made on :- 04/05/13, 04/08/13, 04/10/13

— Technical and water only, no inerts to review.

PRN 11-03 review - Passed

Jacket - Passed

S.S/04-11/13 MRID- 490895

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. <u>All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.</u>

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Ted Head
Phone #: 651-795-5814, 715-808-9834 (cell) Pamco
Email: Ted.Head@ecolab.com

First Call/Initials:	**Second Call/Initials:**	
Date: 04/05/13	**Date:** 04/08/13	04/10/13
Time: 4:45 pm	**Time:** 2:13 pm	7:58 am

This is Srijana Shrestha **, EPA contractor.**

I'm calling regarding your submission in support of the product, "Hydrus EPA Reg# 1677-EUR **.**

We have found the following deficiencies regarding:
PR Notice 2011-3: Yes or No

Volume/Study Title:
Study # 29 missing sign & date of submitter in pg. 2 and pg. 3 missing sign of sponsor & submitter.

Volume/Study Title:
Study # 30 missing sign & date of sponsor in pg. 3

Volume/Study Title:
Study # 31 missing sign & date of sponsor in pg. 3.

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:
If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

Shrestha, Srijana

From: Head, Ted [Ted.Head@ecolab.com]
Sent: Wednesday, April 10, 2013 11:27 AM
To: Shrestha, Srijana
Cc: Koslop, Brandy
Subject: RE: Submission in Support of Product, "Hydris" (EPA Reg# 1677-EUR)
Attachments: 1200041cl4_v02.pdf; 1200041cl2_v02.pdf; 1200041cl3_v02.pdf

Srijana:

Attached please find revised studies to include:

1. Study # 1200041CL4: revised page 2 and 3 with signature and date of Study Sponsor and Submitter.
2. Study # 1200041CL3: Identification of Study Sponsor and Signature.
3. Study # 1200041CL2: Identification of Study Sponsor and Signature.

Please let me know if this will suffice for the application to be submitted to the PM. My office phone is currently not working. Perhaps if we need to talk it is better for you to contact me on my cell at 715-808-9834.

Regards,

Ted Head
Director, Global Innovative Product Registration
Law & Regulatory Affairs

ECOLAB 655 LONE OAK DRIVE, EAGAN, MN 55121
T 651 795 6814 **F** 651 204 7507 **E** ted.head@ecolab.com

From: Shrestha, Srijana [mailto:Shrestha.Srijana@epa.gov]
Sent: Wednesday, April 10, 2013 8:56 AM
To: Head, Ted
Cc: Koslop, Brandy
Subject: Submission in Support of Product, "Hydris" (EPA Reg# 1677-EUR)

Dear Mr. Head:

In regards to deficiencies we discussed earlier, below are my comments:

1) Study # 1200041CL4: I noticed there are 8 pages amendment to the report. To make the report look professional we placed those 8 pages at the back of the report. Hence, Confidentiality page (page 2) is still missing the signature of submitter and date. Also, in the GLP Compliance page i.e pg 3 it is missing signature and date of Study Sponsor and Study Submitter. We cannot replace those pages because it will mess up with the continuous pagination of the study. So, please provide revised pages with signatures.
2) Study # 1200041CL3: I understand GLP compliance statement starts on page 3 and continues to page 4 but our issue is we cannot identify who the sponsor is since the title "Sponsor" is not mentioned in GLP page. So, please provide revised page 3 with signature of "Study Sponsor".
3) Study # 1200041CL2: Likewise, in the GLP compliance statement no title is given as "Study Sponsor" in page 3 and 4 so, we have no way of knowing who the sponsor is for the study. Hence, please provide revised page with study sponsor's signature on it.

I have been trying to reach you through phone since couple of days but could not get hold of you. Please give me a call after you read this email so that we can discuss about these issues and I can clearly explain it to you. Due to the time line we have, I will have to forward your application to PM by 04/11/13 noon. So, please send me corrections before this date. If you have any questions or require additional information, please do not hesitate to contact me.

Thanking you,
Srijana Shrestha
Indus Corporation, EPA Contractor
2777 S. Crystal Drive, S 4826 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060

From: Head, Ted [mailto:Ted.Head@ecolab.com]
Sent: Tuesday, April 09, 2013 4:45 PM
To: Shrestha, Srijana
Cc: Koslop, Brandy
Subject: RE: Submission in Support of Product, "Hydris" (EPA Reg# 1677-EUR)

Srijana:
Thank you for the voice mail and e-mail concerning the studies listed below. Please note the following:

1. Study # 1200041CL4: You will notice with this study that the first 8 pages are an amendment to the report. Page 6 is the no claim of confidentiality and page 7 is the GLP compliance statement. These pages replace pages 2 and 3 of the study. I have attached the amendment to the final report.

2. Study # 1200041CL3: The GLP compliance statement starts on page 3 and continues to page 4 where you will find the signature and date of the study sponsor. I have attached pages 3-4.

3. Study # 1200041CL2: Likewise, the GLP compliance statement starts on page 3 and continues to page 4 where you will find the signature and date of the study sponsor. I have attached pages 3-4.

I trust that this has resolved the pending issues for EPA reg. No. 1677-EUR. If you have any further questions please do not hesitate to contact me at 651-795-5770.

Regards,

Ted Head
Director, Global Innovative Product Registration
Law & Regulatory Affairs

ECOLAB 655 LONE OAK DRIVE, EAGAN, MN 55121
T 651 795 6814 **F** 651 204 7507 **E** ted.head@ecolab.com

From: Shrestha, Srijana [mailto:Shrestha.Srijana@epa.gov]
Sent: Monday, April 08, 2013 2:24 PM
To: Head, Ted
Subject: Submission in Support of Product, "Hydris" (EPA Reg# 1677-EUR)

Dear Mr. Head:

This is regarding your submission in support of the product, "Hydris" (EPA Reg# 1677-EUR). We have found following issue with your submission:

4) Study #29 (MRID 490895-29) with Study # 1200041 CL4 as per your transmittal has page 2 which is missing the signature of submitter and date. Also, in the page 3 it is missing signature and date of Study Sponsor and Study Submitter.
5) Study #30 (MRID 490895-30) with Sponsor Study # 1200041 CL3 as per your transmittal is missing the signature and date of Study Sponsor in page 3.
6) Study # 31 (MRID 490895-31) with Sponsor Study # 1200041 CL2 is missing the signature and date of Study Sponsor in page 3.

We are still reviewing your submission and will contact if we find further issues with it. Please send revised pages to me by email. If you have any questions or require additional information, please do not hesitate to contact me.

Thanking you,
Srijana Shrestha
Indus Corporation, EPA Contractor
2777 S. Crystal Drive, S 4826 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060

CONFIDENTIALITY NOTICE:
This e-mail communication and any attachments may contain proprietary and privileged information for the use of the designated recipients named above.
Any unauthorized review, use, disclosure or distribution is prohibited.
If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explodability	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 29, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-477008
EPA File Symbol or Registration Number: 1677-EUR
Product Name: HYDRIS
EPA Receipt Date: 27-Mar-2013
EPA Company Number: 1677
Company Name: ECOLAB INC.

TED HEAD
ECOLAB INC.
370 NORTH WABASHA STREET
ST. PAUL, MN 55102

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9329344~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 32

Receipt No. S-	932934
EPA File Symbol/Reg. No.	1677-EUR
Pin-Punch Date:	3/27/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A532

Granted: A540

Amount Due: $ 4,631.00

Technical & water only. no inerts. SS/04-19-13

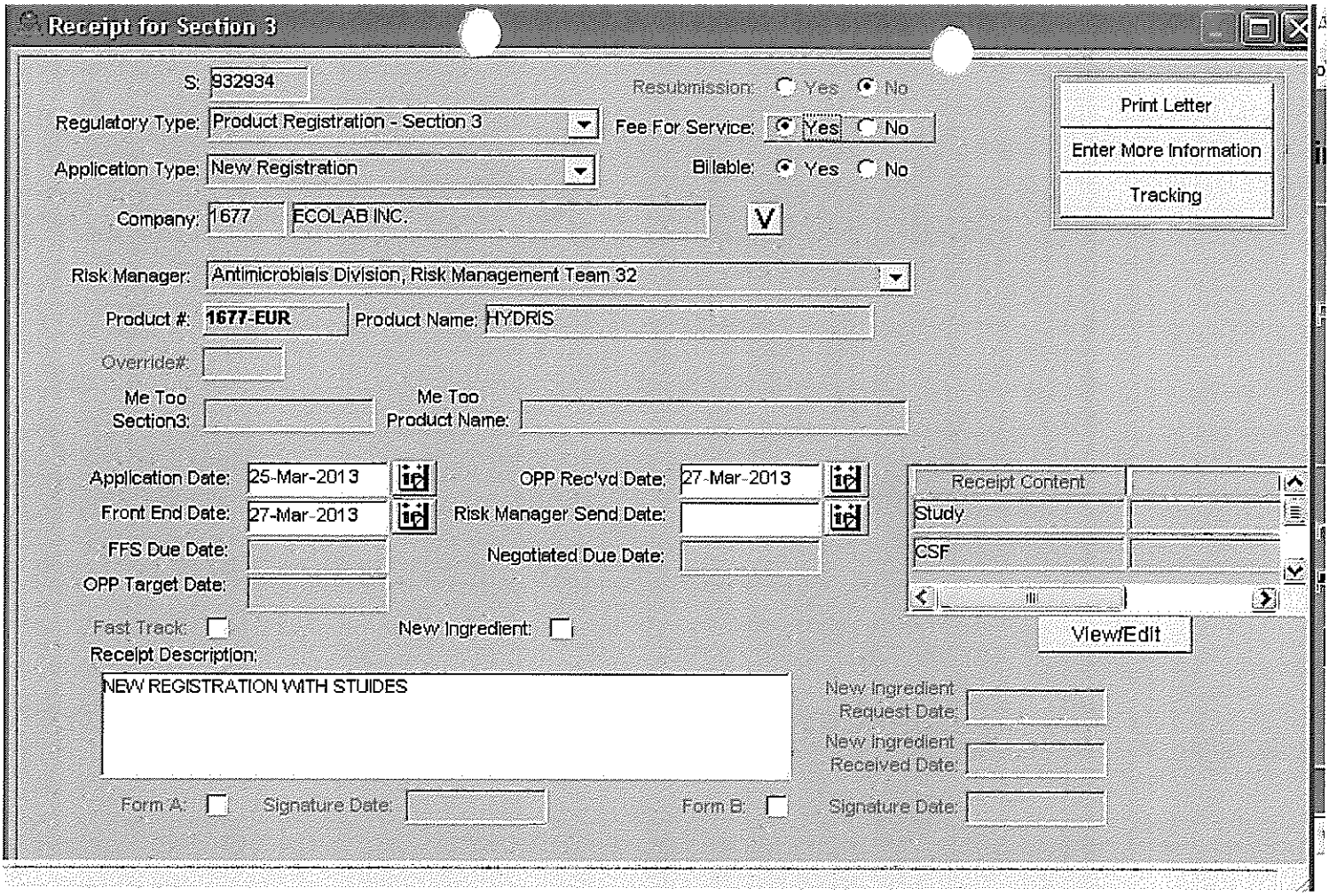
Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 1 (Denson) Date: 3-

Remarks:

- The company is proposing to register an end use product
- In addition to submitting acute tox & product chemistry data, the company also submitted efficacy data.
- For A532 submissions, PRIA Fee table states if efficacy submitted it does not belong in A532 category.


Receipt for Section 3
S: 932934
Resubmission: Yes No
Print Letter
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Enter More Information
Application Type: New Registration
Billable: Yes No
Tracking
Company: 1677 ECOLAB INC.
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 1677-EUR
Product Name: HYDRIS
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 25-Mar-2013
OPP Rec'vd Date: 27-Mar-2013
Front End Date: 27-Mar-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
NEW REGISTRATION WITH STUDIES
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Head, Ted

From: paygovadmin@mail.doc.twai.gov
Sent: Monday, March 25, 2013 11:12 AM
To: Head, Ted
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

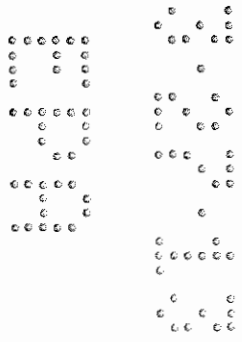
Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25A38R9L
Agency Tracking ID: 74427166007
Transaction Type: Sale
Transaction Date: Mar 25, 2013 12:12:16 PM

Account Holder Name: Theodore Head
Transaction Amount: $4,631.00
Billing Address: 840 Kirkwood Way
City: Hudson
State/Province: WI
Zip/Postal Code: 54016
Country: USA
Card Type: MasterCard
Card Number: **********4677

Decision Number:
Registration Number:
Company Name: Ecolab Inc
Company Number: 1677
Action Code: A532

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



Please read instructions on reverse before comple[illegible]

Approved. OMB No. 2070-0060 Approval Expires 5-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1677-[pending]	Monisha Harris	☒ None ☐ Restricted
3. Company/Product (Name) **Hydris**	PM# 32	

5. Name and Address of Applicant (Include ZIP Code)
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Final printed labels in response to
☐ Resubmission in response to Agency letter dated
☐ "Me Too" Application.
☐ Notification - Explain below.
☒ Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)
New registration.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)_____
**** Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Package wgt. / No. Per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1 gallon, 5 gallon, 55 gallon, tote	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted if necessary to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Theodore Head	**Director Global Product Registration**	**(651) 795-6814**

Certification

I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
[signature]	**Director Global Product Registration**	
4. Typed Name Theodore D. Head	5. Date 3-25-13	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White - EPA File Copy (original)

Yellow - Applicant Copy

ECOLAB

Theodore Head
DIRECTOR GLOBAL PRODUCT REGISTRATION

T 651 795 6814
F 651 225 3122

370 WABASHA STREET NORTH
ST. PAUL, MN 55102-1390
Ted.Head@ecolab.com

March 25, 2013

Document Processing Desk (E-SUB)
Office of Pesticide Programs (7502P)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Monisha Harris, PM-32

Re: Hydris
EPA Reg. No. [1677-pending]

Dear Monisha:

Ecolab Inc. is requesting a new pesticide registration for the above-named product. Enclosed you will find all the required EPA forms, data and certification of PRIA Fee Payment.

We believe that this submission falls into PRIA Category A532 New End Use Product that uses registered source of the active ingredient with a 5 month review and $4,631 PRIA Fee.

A brief background on the entirety of this project will help facilitate the Agency in its review. On February 1, 2013 the Agency received a registration submission from Ecolab called Hydris Mineral Activator Tablet (OPP Decision Number D-474712, EPA Reg. No. 1677-EUN).

The Hydris Mineral Activator Tablet will be used with a pesticide device that has a three chamber electrolytic cell to generate a sodium hypochlorite solution to be used onsite with no sale or distribution. Ecolab had meet with Dennis Edwards on June 7, 2012 to discuss regulatory pathway and we were advised that if distribution and sale of the salt tablet was intended then registration of the salt tablet (Hydris Mineral Activator Tablet) would be required as an MUP. We also had guidance from Mark Hartman on October 21, 2011 that registration of the bleach solution output from the EPA device would also be acceptable and that other registrants had previously pursued this pathway. This submission addresses the End Use Product Hydris (output from device) that we had indicated would follow the MUP submission the Agency received in February. From a diagram perspective it looks like the following.

EPA Registered MUP (1677-EUN submitted 2/1/13) → Pesticide Device → EPA Registered EUP (This Submission)

I would also like to point out that many of study names for prdoduct chemistry, efficacy and toxicity were conducted on a products called Aqualogic or XY-12.

Aqualogic is identical to Hydris. Hydris is the commercial name from our marketing group while Aqualogic was the project name from the R&D team.

XY-12 / Ultra San (EPA Reg. No. 1677-52) is the same formula as Hydris just at a higher concentration. Accordingly the toxicity data at the higher concentration is being used to bridge down to the Hydris submission with a lower concentration.

I trust that this additional information will be useful in the review of this application and the End Use Product submission to follow in March. Please do not hesitate to contact me if you require any additional information or have any questions about this submission.

Sincerely,

Theodore D. Head
Director Global Product Registration
Law & Regulatory Affairs

TRANSMITTAL DOCUMENT

Name and Address	Ecolab Inc 370 Wabasha Street North St. Paul MN 55102
Regulatory action in support of Which this package is submitted:	Hydris
EPA Reg. No./File Symbol:	1677-[pending]
Transmittal Date:	03-25-13

Volume No.	Citation	MRID Number

1. Product Chemistry

Davis (2012) Aqualogic
Chemical Characterization
OPPTS Guidelines 830.1550 - 830.7950
Ecolab Study No. 1200040 64 pages total. _____

Davis (2012) Aqualogic Day Tank Ambient
Chemical Characterization OPPTS Guidelines 830.6317, 6320
Ecolab Study No. 1200020 22 pages total. _____

Davis (2012) Aqualogic Ambient (Disinfectant)
Chemical Characterization OPPTS Guidelines 830.6317, 6320
Ecolab Study No. 1200017 29 pages total. _____

Davis (2012) Aqualogic 715 ppm Ambient (Sanitizer)
Chemical Characterization OPPTS Guidelines 830.6317, 6320
Ecolab Study No. 1200018 35 pages total. _____

Davis (2012) Aqualogic Refrigerated (Disinfectant)
Chemical Characterization OPPTS Guidelines 830.6317, 6320
Ecolab Study No. 1200019 38 pages total. _____

2. Efficacy Studies

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Rinovirus Type 37 260 ppm
Ecolab Inc, Study No. 1200063. 69 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Rinovirus Type 37 660 ppm
Ecolab Inc, Study No. 1200062. 59 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Norovirus 660 ppm
Ecolab Inc, Study No. 1200066. 68 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Norovirus 260 ppm
Ecolab Inc, Study No. 1200067. 73 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Herpes Simplex Type 1
Ecolab Inc, Study No. 1200064. 59 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Influenza A Virus -260 ppm
Ecolab Inc, Study No. 1200061. 63 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 GSP Hospital Disinfection
Ecolab Inc, Study No. 1200052. 67 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Non-Food Contact Sanitizing 4 mins
Ecolab Inc, Study No. 1200054. 70 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Non-Food Contact Sanitizing 1 min
Ecolab Inc, Study No. 1200053. 72 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Influenza A Virus 660 ppm
Ecolab Inc, Study No. 1200060. 52 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 HIV Type 1
Ecolab Inc, Study No. 1200074CL6. 29 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Rotavirus
Ecolab Inc, Study No. 1200074CL2. 36 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Vaccinia virus
Ecolab Inc, Study No. 1200074CL1. 29 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 RSV
Ecolab Inc, Study No. 1200074CL3. 28 pages total. _____

Hellickson (2012) Aqualogic
OCSPP Guideline 810.2200 Adenovirus Type 5
Ecolab Inc, Study No. 1200059. 57 pages total. _____

Miller (2012) Aqualogic
OCSPP Guideline 810.2200 Human Coronavirus
Ecolab Inc, Study No. 1200074CL5. 28 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 MNV-1
Ecolab Inc, Study No. 1200074CL4. 29 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Hepatitis B Virus
Ecolab Inc, Study No. 1200074CL7. 31 pages total. _____

Conway (2012) Aqualogic
OCSPP Guideline 810.2200 Herpes Simplex Type 2
Ecolab Inc, Study No. 1200074CL8. 29 pages total. _____

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 Antibiotic Resistant Organisims
Ecolab Inc, Study No. 1200073. 92 pages total. _____

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 GSP 10 minutes
Ecolab Inc, Study No. 1200077. 59 pages total. _____

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 T. mentagrophytes, A. niger
Ecolab Inc, Study No. 1200058. 75 pages total. _____

Holen (2013) Aqualogic
OCSPP Guideline 810.2200 GSP
Ecolab Inc, Study No. 1200072. 87 pages total. _____

3. Toxicity Studies

Smith (2013) XY-12 Acute Inhalation Toxicity
Health Effects Test Guidelines –OPPTS 870.1300
Ecolab Inc, Study No. 1200041CL4. 100 pages total. _____

Vasquez (2013) XY-12 Contact Sensitization
Health Effects Test Guidelines –OPPTS 870.2600
Ecolab Inc, Study No. 1200041CL3. 59 pages total. _____

Vasquez (2013) XY-12 Acute Dermal Toxicity
Health Effects Test Guidelines –OPPTS 870.1200
Ecolab Inc, Study No. 1200041CL1. 56 pages total. _____

Vasquez (2013) XY-12 Acute Oral Toxicity
Health Effects Test Guidelines –OPPTS 870.1100
Ecolab Inc, Study No. 1200041CL1. 49 pages total. _____

Vasquez (2012) XY-12 Primary Eye Irritation Use Dilution
Health Effects Test Guidelines –OPPTS 870.2400
Ecolab Inc, Study No. 1100052CL2. 56 pages total. _____

Vasquez (2012) XY-12 Primary Dermal Irritation Use Dilution
Health Effects Test Guidelines –OPPTS 870.2500
Ecolab Inc, Study No. 1100052CL1. 53 pages total. _____

Company Official:	Theodore D. Head, Director Global Registrations	
Company Name:	Ecolab Inc	
Company Contact:	Theodore D. Head	Phone: (651) 795-6814

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Ecolab Inc. 370 Wabasha St. N St. Paul, MN 55102	1677-[pending]
	Product Name Hydris
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 03/25/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Sodium Hypochlorite

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Sodium Chloride	Hydris Mineral Activator Tablet	1677-EUN

Signature	Name and Title	Date
[signature]	Ted Head - Dir, Product Registration	3-25-13

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ecolab Inc., 370 N. Wabasha St., St. Paul, MN 55102-1390	EPA Registration Number/File Symbol 1677-[pending]
Active Ingredient(s) and/or representative test compound(s) Sodium Hypochlorite	Date 3-20-13
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) institutional, commercial, industrial	Product Name Hydris

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	3-20-13	Theodore Head, Director Product Registration

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date March 14, 2013	EPA Reg.No./File Symbol 1677-[pending] Page 1 of 3
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity		Ecolab Inc.	OWN	
830.1600	Description of beginning materials		Ecolab Inc.	OWN	
830.1620	Description of formulation process		Ecolab Inc.	OWN	
830.1670	Discussion of Formation of Impurities		Ecolab Inc.	OWN	
830.1700	Preliminary Analysis		Ecolab Inc.	OWN	
830.1750	Certification of limits		Ecolab Inc.	OWN	
830.1800	Enforcement Analytical Method		Ecolab Inc.	OWN	
830.6302	Color		Ecolab Inc.	OWN	
830.6303	Physical state		Ecolab Inc.	OWN	
830.6304	Odor		Ecolab Inc.	OWN	
830.6314	Oxidation Reduction		Ecolab Inc.	OWN	
830.6315	Flamability		Ecolab Inc.	OWN	
830.6316	Expoladability		Ecolab Inc.	OWN	
830.6317	Storage Stability Long Term		Ecolab Inc.	OWN	
830.6319	Miscibility		Ecolab Inc.	OWN	
830.6320	Corrosion characteristics Long term		Ecolab Inc.	OWN	
830.6321	Dielectric Breakdown		Ecolab Inc.	OWN	
830.7000	pH		Ecolab Inc.	OWN	
830.7100	Viscosity		Ecolab Inc.	OWN	
830.7300	Density		Ecolab Inc.	OWN	

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-25-13

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DATA MATRIX

Date March 14, 2013	EPA Reg.No./File Symbol 1677-[Pending]	Page 2 of 3
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris	

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity		Ecolab Inc.	OWN	
870.1200	Acute dermal toxicity		Ecolab Inc.	OWN	
870.1300	Acute inhalation		Ecolab Inc.	OWN	
870.2400	Acute eye irritation		Ecolab Inc.	OWN	
870.2500	Acute skin irritation		Ecolab Inc.	OWN	
870.2600	Dermal sensitization		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200072		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200058		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200077 (10 minutes)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200073 (antibiotic resistant organisims)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL8 (Herpes simplex Virus Type 2)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL7 (Hepatitis B Virus)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL4 (Murine Norovirus)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL5 (Human Coronavirus)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200059 (Adenovirus Type 5)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL3 (Respiratory syncytial virus)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL1 (Vaccinia virus)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL2 (Roravirus)		Ecolab Inc.	OWN	
810.2200	Virucidal Efficacy Study #1200074CL6 (HIV Type 1)		Ecolab Inc.	OWN	

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-25-13

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DATA MATRIX

Date March 14, 2013	EPA Reg.No./File Symbol 1677-[Pending]
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	Disinfectants for use on Hard Surfaces Study #1200060 (Influenza A 660 ppm)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200053 (Non-food contact 1 minute)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200054 (Non-food contact 4 minute)		Ecolab Inc.	OWN	
810.2200	Germicidal Spray Study #1200052 (Hospital Disinfection)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200061 (Influenza A 260 ppm)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200064 (Herpes Virus Type 1)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200067 (Norovirus 260 ppm)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200066 (Norovirus 660 ppm)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200062 (Rhinovirus Type 37 660 ppm)		Ecolab Inc.	OWN	
810.2200	Disinfectants for use on Hard Surfaces Study #1200063 (Rhinovirus Type 37 260 ppm)		Ecolab Inc.	OWN	

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-20-13

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Date March 14, 2013	EPA Reg.No./File Symbol 1677-[pending]	Page 1 of 3
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris	

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-25-13

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Date March 14, 2013	EPA Reg.No./File Symbol 1677-[Pending]	Page 2 of 3
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris	

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-25-13

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DATA MATRIX

Date March 14, 2013	EPA Reg.No./File Symbol 1677-[Pending]	Page 3 of 3
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102	Product Hydris	

Ingredient: Sodium Hypochlorite

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title Theodore Head Director Golbal Product Registration & Compliance	Date 3-25-13

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Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
1677-XXX	3-25-13	001677-00XXX.20130325_v01.intial.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

3-25-13
Date

Theodore Head
Name (typed)

Director Global Product Registrations
Title

There is an **ELECTRONIC LABEL** for this action

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AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

Hydris™

Disinfectant, Sanitizer, Virucide, Fungicide, Mildewcide, Bactericide, Cleaner, Deodorizer

Active Ingredients:

Sodium Hypochlorite	0.0866%
Inert Ingredients	99.9134%
Total	100.00%

Available Chlorine: 0.0825% Free Available Chlorine FAC

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Harmful if absorbed through skin or swallowed Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Mixing this product with acid or ammonia will release chlorine gas.

Do not mix solution with other cleaning products.

Do not use solution with acidic toilet-bowl cleaners, or bathroom/shower cleaning products.

Do not use solution on wool or natural carpet fibers.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Solution(s) are efficacious for up to 7 days from filling. After 7 days, empty and refill with fresh solution. Always use a clean Hydris™ spray bottle when filling this product.

Solution can be used immediately or stored in a closed Ecolab approved container in a cool, dark area for a period of 5 months. Once opened within this time period, the solution must be used immediately.

Hydris™ Disinfectant Cleaner is intended for use in commercial, institutional and hospitality housekeeping. It cleans, deodorizes and kills germs in one step.

Hydris™ Disinfectant Cleaner is designed for use in

- Hotel/motel housekeeping
- Commercial building routine cleaning of hard surfaces and floors
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.
- Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.
- Cleaning and disinfecting hospitals, assisted living facilities, long term care centers, nursing homes and medical clinics.

Spray solution onto hard, non-porous surface, thoroughly wetting surfaces, Hold sprayer 6-8 inches from the surface. Spread solution with a disposable, cotton or microfiber wipe, sponge, or cloth. Allow surface to remain wet for time indicated. No rinsing necessary.

BACTERICIDAL / DISINFECTANT in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria according to the AOAC Germicidal Spray Test in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Acinetobacter baumannii (ATCC 19606), *Acinetobacter baumannii* (MDR) (ATCC BAA-1605), *Escherichia coli* (ATCC 11229), *Klebsiella pneumonia* (ATCC 4352), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Serratia marcescens* (ATCC 14756), *Shigella flexneri* (ATCC 9380), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus aureus* (VISA) (ATCC 700788), *Staphylococcus aureus* (CA-MRSA) (ATCC BAA - 1683), *Staphylococcus aureus* (MRSA) (ATCC 33592), *Klebsiella pneumonia (Carapenum-resistant)* (ATCC BAA-1705), *Enterobacter aerogenes* (ATCC 13048),*Enterococcus faecalis* (ATCC 29212), *Streptococcus pyogenes* (ATCC 19615), *Shigella dysenteriae* (ATCC 29026), *Listeria Monocytogenes* (ATCC 7644).

BACTERICIDAL / DISINFECTANT in 10 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Enterococcus faecalis (VRE) (ATCC 51299) and *Escherichia coli* 0157:H7(ATCC 43895)

NON-FOOD CONTACT SURFACE SANITIZING in 1 minutes 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

NON-FOOD CONTACT SURFACE SANITIZING in 4 minutes at 273 ppm sodium hypochlorite (260 Free Available Chlorine) in 250 ppm hard water against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

VIRUCIDAL in 30 seconds at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Influenza A virus H1N1Strain (ATCC VR-1736), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Murine Norovirus (Strain MNV-1.CW1), Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Herpes Simplex Virus Type I (ATCC VR-733 Strain F), Herpes Simplex Virus Type II (ATCC VR-734, Strain G), HIV-1 (Strain HTLV-III_B).

VIRUCIDAL in 30 seconds at 273 ppm sodium hypochlorite (260 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum and 400 ppm hard water on hard, non-porous surfaces against the following organisms.

Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Influenza A virus H1N1Strain (ATCC VR-1736),

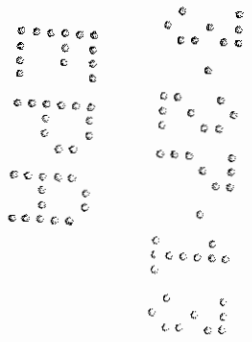
VIRUCIDAL in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Adenovirus Type 5 (ATCC VR-5), Hepatitus B Virus (HBV), Human Coronavirus (ATCC VR-740), Respiratory Syncytial Virus (RSV) (ATCC VR-26), Rotavirus (Strain WA), Vaccinia Virus (ATCC VR-119).

This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1Influenza A virus.

FUNGICIDAL in 10 minutes at 866 ppm sodium hypochlorite 825 ppm Free Available Chlorine) according to the AOAC Fungicidal Test in the presence of 5% blood serum on hard, non-porous surfaces against *Trichophyton mentagrophytes* (ATCC 9533), and *Aspergilus niger* (ATCC 6275).

DEODORIZER Apply solution with sprayer, cloth, mop, auto-scrubber, or carpet extractor to surfaces harboring odor-causing bacteria.



STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: RESIDUE REMOVAL INSTRUCTIONS: For containers less than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

Net Contents:

Manufactured by:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-[pending]
EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 5389-NC-1 (G) 1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V),

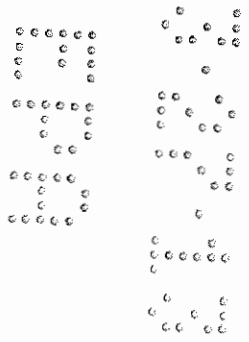
58046-TX-2 (X)

Superscript refers to first letter of date code

Optional Marketing Language

- Cleans every day dirt and soils from surfaces
- Deodorizes – or - Deodorizer
- Easy to use
- Eliminates odors
- Eliminates odors caused by [bacteria] [germs] [mildew]
- Leaves [bathroom(s)] [restroom(s)] [locker room(s)] [surfaces][clean and] sanitary
- Leaves behind a fresh clean smell – or - fragrance
- Low odor [formula – or- profile]
- No PPE [Personal Protective Equipment] required
- No rinsing necessary
- One-step cleaner [and disinfectant]
- Removes –or- eliminates odors [at the source]
- Streak-free [formula –or- clean]
- Effective against odor causing bacteria
- [This product is] VOC [Volatile Organic Compounds] compliant
- [This product] Contains no NPEs [Nonylphenol ethoxylates]
- [This product is] Phosphate free
- Leaves surfaces sanitized
- Sanitizer
- Sanitizes surfaces
- Sanitizes hard, nonporous surfaces
- Antibacterial [action]
- Bacteria-fighting - or – Germ-fighting formula
- Bactericide – or Bactericidal
- Restroom – or- bathroom disinfectant
- Broad spectrum disinfectant [cleaner]
- Cleans and disinfects
- Cleans and disinfects within 5 minutes Cleaner and disinfectant in one
- Cleans – and/or – disinfects [bathroom] [school] [classroom] [restroom] [locker room] [office] [work – or- office place] [environment] [place] [surfaces] [floors] [table - or- desk tops] [hard surfaces] [railings] -and/or- deodorizes
- Disinfects
- Disinfects and deodorizes by killing common [germs – or – bacteria] and controlling their odors
- Disinfects as it cleans
- Disinfects nonporous [hard] surfaces

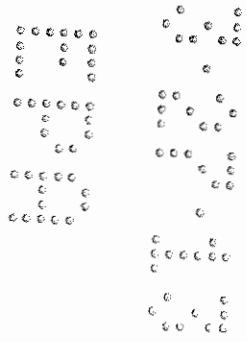
- Easily [cleans] [deodorizes] [sanitizes] [disinfects]
- [Effective] disinfectant [in the presence of 5% serum load – or – organic soil]
- Germicide – or Germicidal
- Institutional disinfectant
- Kills 99.9% of bacteria –and/or – germs
- Kills 99.9% of bacteria – and/or germs commonly found in –or- on [the] [list any use site]
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] –and/or – destroy[s] [the] cold virus – and/or – flu virus – and/or – cold and flu virus[es] – and/or viruses that can cause cold - and/or flu
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] – and/or- and/or – destroy[s] Methicillin-resistant Staphylococcus aureus [(MRSA)] –and/or – Community Acquired Methicillin-resistant Staphylococcus aureus [(CA-MRSA)]
- Kills cold and flu virus
- Kills germs while it cleans
- Kills Pandemic 2009 H1N1 Influenza A virus [(formerly called swine flu)]
- Multipurpose disinfectant
- One-step cleaner [and disinfectant]
- Antifungal
- Fungicidal –or- Fungicide
- Kills mold and mildew
- Kills athlete's foot fungus
- Mildewcidal –or- Mildewcide
- Removes –and/or – cuts through – and/or- tough on mold –and/or mildew
- Disinfectant
- Non-Food Contact Sanitizer
- Kills 99.9% of Bacteria in 60 seconds
- Effective in the Presence of 5% organic soil Contamination
- One-step Disinfectant/Cleaner
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Hospital Disinfectant
- Sanitizer
- Kills 99.9% of Bacteria
- Effective in the Presence of 5% organic soil contamination
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Effective One-step Sanitizer/Cleaner in hard water up 250 ppm hardness.
- Commercial building routine cleaning of hard surfaces, including glass/mirror surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.



- Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.
- Commercial building routine cleaning of hard surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

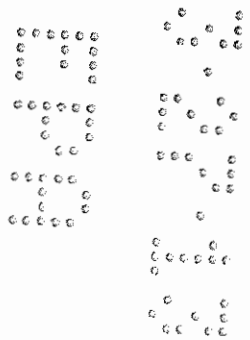
USE LOCATIONS: [Where to use this product] [For use around – or- in –or- throughout the]

- Assisted Living Facilities
- Athletic Facility[Facilities]
- Bathroom[s]
- Business[es]
- Commercials Building[s]
- Daycare Center[s] –or- Childcare Center[s]
- Fitness Center[s]
- Government Building[s]
- Health Club[s]
- Healthcare [facilities]
- Hospital[s]
- Hotel[s]
- Institutions
- Laboratories
- Lodging
- Locker Room[s]
- Long Term Care Center[s]
- Medical Facilities
- Motel[s]
- Office[s] [Buildings]
- Patient Care Area[s]
- Recreational Center[s] –or- Facility [Facilities]
- Retail Center[s]
- School[s] –an/or University[Universities] – and/or- Colleges



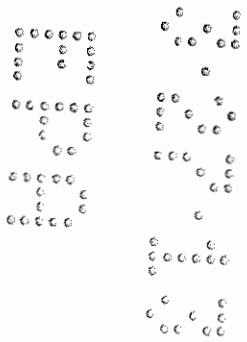
USE SITES: [For] Use on [hard,] [nonporous surface] – or - **T**he product will not damage-or- harm

- [Bath] Tubs
- [Classroom] Desks
- Countertops
- Counter[s]
- Diaper Changing Table[s]
- Diaper Pail[s]
- [Door] Knobs
- Elevator[s]
- Fixture[s]
- Examination **T**ables –and/or- Beds
- Floors
- Glass –and/or- Mirror Surfaces
- Hard [Non-porous] Surfaces
- High-Touch Point[s]
- Patient Bed[s] –and/or Rail[s]
- [Play] Tables[s] –and/or- Stations
- Shower Curtain[s]
- Shower stall[s]
- Shower[s]
- Sink[s]
- Table[s]
- Toilet[s]
- Urinal[s]
- [Water] [Drinking] Fountain
- [Washable] Chair[s]
- [Washable] Walls



USE SURFACES:

- ABS [Acrylonitrile butadiene styrene] [plastic]
- Aluminum
- [Brushed] [Polished] Nickel
- [Brushed] Bronze
- Carpet (50 ppm FAC –or- 52 ppm sodium hypochlorite solution only), test in an inconspicuous spot first
- Glass
- Sealed Granite
- Hard, non-porous surfaces –or environmental surfaces
- Limestone
- Melamine
- Mirror
- [Polished] Chrome
- Polyacrylic
- Polycarbonate
- Polyethylene
- Polypropylene
- Slate
- Stainless Steel [304]
- Terrazzo
- To avoid possibility of discoloration, avoid prolonged contact of the 825 ppm FAC or 866 ppm sodium hypochlorite solution with certain metals (such as brass, steel), and marble surfaces.



Hydris™

Disinfectant, Sanitizer, Virucide, Fungicide, Mildewcide, Bactericide, Cleaner, Deodorizer

Active Ingredients:

Sodium Hypochlorite	0.0866%
Inert Ingredients	99.9134%
Total	100.00%

Available Chlorine: 0.0825% Free Available Chlorine FAC

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Harmful if absorbed through skin or swallowed Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Mixing this product with acid or ammonia will release chlorine gas.

Do not mix solution with other cleaning products.

Do not use solution with acidic toilet-bowl cleaners, or bathroom/shower cleaning products.

Do not use solution on wool or natural carpet fibers.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

DIRECTIONS FOR USE

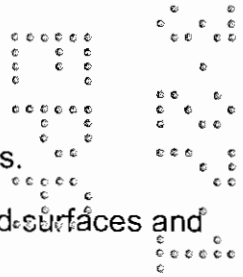
It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Solution(s) are efficacious for up to 7 days from filling. After 7 days, empty and refill with fresh solution. Always use a clean Hydris™ spray bottle when filling this product.

Solution can be used immediately or stored in a closed Ecolab approved container in a cool, dark area for a period of 5 months. Once opened within this time period, the solution must be used immediately.

Hydris™ Disinfectant Cleaner is intended for use in commercial, institutional and hospitality housekeeping. It cleans, deodorizes and kills germs in one step.

Hydris™ Disinfectant Cleaner is designed for use in



Hotel/motel housekeeping

Commercial building routine cleaning of hard surfaces and floors.

Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.

Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.

Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

Cleaning and disinfecting hospitals, assisted living facilities, long term care centers, nursing homes and medical clinics.

Spray solution onto hard, non-porous surface, thoroughly wetting surfaces, Hold sprayer 6-8 inches from the surface. Spread solution with a disposable, cotton or microfiber wipe, sponge, or cloth. Allow surface to remain wet for time indicated. No rinsing necessary.

BACTERICIDAL / DISINFECTANT in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria according to the AOAC Germicidal Spray Test in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Acinetobacter baumannii (ATCC 19606), *Acinetobacter baumannii* (MDR) (ATCC BAA-1605), *Escherichia coli* (ATCC 11229), *Klebsiella pneumonia* (ATCC 4352), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Serratia marcescens* (ATCC 14756), *Shigella flexneri* (ATCC 9380), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus aureus* (VISA) (ATCC 700788), *Staphylococcus aureus* (CA-MRSA) (ATCC BAA - 1683), *Staphylococcus aureus* (MRSA) (ATCC 33592), *Klebsiella pneumonia (Carapenum-resistant)* (ATCC BAA-1705), *Enterobacter aerogenes* (ATCC 13048),*Enterococcus faecalis* (ATCC 29212), *Streptococcus pyogenes* (ATCC 19615), *Shigella dysenteriae* (ATCC 29026), *Listeria Monocytogenes* (ATCC 7644).

BACTERICIDAL / DISINFECTANT in 10 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Enterococcus faecalis (VRE) (ATCC 51299) and *Escherichia coli* 0157:H7(ATCC 43895)

NON-FOOD CONTACT SURFACE SANITIZING in 1 minutes 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

NON-FOOD CONTACT SURFACE SANITIZING in 4 minutes at 273 ppm sodium hypochlorite (260 Free Available Chlorine) in 250 ppm hard water against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

VIRUCIDAL in 30 seconds at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Influenza A virus H1N1Strain (ATCC VR-1736), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Murine Norovirus (Strain MNV-1.CW1), Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Herpes Simplex Virus Type I (ATCC VR-733 Strain F), Herpes Simplex Virus Type II (ATCC VR-734, Strain G), HIV-1 (Strain HTLV-III_B).

VIRUCIDAL in 30 seconds at 273 ppm sodium hypochlorite (260 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum and 400 ppm hard water on hard, non-porous surfaces against the following organisms.

Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Influenza A virus H1N1Strain (ATCC VR-1736),

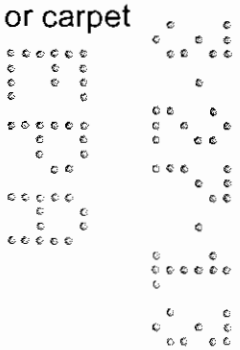
VIRUCIDAL in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Adenovirus Type 5 (ATCC VR-5), Hepatitus B Virus (HBV), Human Coronavirus (ATCC VR-740), Respiratory Syncytial Virus (RSV) (ATCC VR-26), Rotavirus (Strain WA), Vaccinia Virus (ATCC VR-119).

This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1Influenza A virus.

FUNGICIDAL in 10 minutes at 866 ppm sodium hypochlorite 825 ppm Free Available Chlorine) according to the AOAC Fungicidal Test in the presence of 5% blood serum on hard, non-porous surfaces against *Trichophyton mentagrophytes* (ATCC 9533), and *Aspergilus niger* (ATCC 6275).

DEODORIZER Apply solution with sprayer, cloth, mop, auto-scrubber, or carpet extractor to surfaces harboring odor-causing bacteria.



STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: RESIDUE REMOVAL INSTRUCTIONS: For containers less than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

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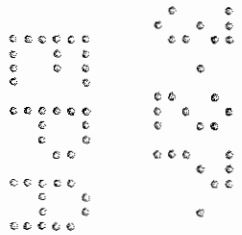

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1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V),

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Superscript refers to first letter of date code

Optional Marketing Language

- Cleans every day dirt and soils from surfaces
- Deodorizes – or - Deodorizer
- Easy to use
- Eliminates odors
- Eliminates odors caused by [bacteria] [germs] [mildew]
- Leaves [bathroom(s)] [restroom(s)] [locker room(s)] [surfaces][clean and] sanitary
- Leaves behind a fresh clean smell – or - fragrance
- Low odor [formula – or- profile]
- No PPE [Personal Protective Equipment] required
- No rinsing necessary
- One-step cleaner [and disinfectant]
- Removes –or- eliminates odors [at the source]
- Streak-free [formula –or- clean]
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- [This product is] VOC [Volatile Organic Compounds] compliant
- [This product] Contains no NPEs [Nonylphenol ethoxylates]
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- Leaves surfaces sanitized
- Sanitizer
- Sanitizes surfaces
- Sanitizes hard, nonporous surfaces
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- Bacteria-fighting - or – Germ-fighting formula
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- Broad spectrum disinfectant [cleaner]
- Cleans and disinfects
- Cleans and disinfects within 5 minutes Cleaner and disinfectant in one
- Cleans – and/or – disinfects [bathroom] [school] [classroom] [restroom] [locker room] [office] [work – or- office place] [environment] [place] [surfaces] [floors] [table – or- desk tops] [hard surfaces] [railings] -and/or- deodorizes
- Disinfects
- Disinfects and deodorizes by killing common [germs – or – bacteria] and controlling their odors
- Disinfects as it cleans
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- Easily [cleans] [deodorizes] [sanitizes] [disinfects]
- [Effective] disinfectant [in the presence of 5% serum load – or – organic soil]
- Germicide – or Germicidal
- Institutional disinfectant
- Kills 99.9% of bacteria –and/or – germs
- Kills 99.9% of bacteria – and/or germs commonly found in –or- on [the] [list any use site]
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] –and/or – destroy[s] [the] cold virus – and/or – flu virus – and/or – cold and flu virus[es] – and/or viruses that can cause cold - and/or flu
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] – and/or- and/or – destroy[s] Methicillin-resistant Staphylococcus aureus [(MRSA)] –and/or – Community Acquired Methicillin-resistant Staphylococcus aureus [(CA-MRSA)]
- Kills cold and flu virus
- Kills germs while it cleans
- Kills Pandemic 2009 H1N1 Influenza A virus [(formerly called swine flu)]
- Multipurpose disinfectant
- One-step cleaner [and disinfectant]
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- Fungicidal –or- Fungicide
- Kills mold and mildew
- Kills athlete's foot fungus
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- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Hospital Disinfectant
- Sanitizer
- Kills 99.9% of Bacteria
- Effective in the Presence of 5% organic soil contamination
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Effective One-step Sanitizer/Cleaner in hard water up 250 ppm hardness.
- Commercial building routine cleaning of hard surfaces, including glass/mirror surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.

- Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.
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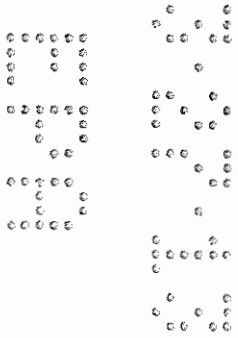
- Government Building[s]
- Health Club[s]
- Healthcare [facilities]
- Hospital[s]
- Hotel[s]
- Institutions
- Laboratories
- Lodging
- Locker Room[s]
- Long Term Care Center[s]
- Medical Facilities
- Motel[s]
- Office[s] [Buildings]
- Patient Care Area[s]
- Recreational Center[s] –or- Facility [Facilities]
- Retail Center[s]
- School[s] –an/or University[Universities] – and/or- Colleges

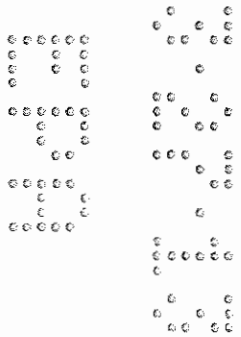
USE SITES: [For] Use on [hard,] [nonporous surface] – or - The product will not damage-or- harm

- [Bath] Tubs
- [Classroom] Desks
- Countertops
- Counter[s]
- Diaper Changing Table[s]
- Diaper Pail[s]
- [Door] Knobs
- Elevator[s]
- Fixture[s]
- Examination Tables –and/or- Beds
- Floors
- Glass –and/or- Mirror Surfaces
- Hard [Non-porous] Surfaces
- High-Touch Point[s]
- Patient Bed[s] –and/or Rail[s]
- [Play] Tables[s] –and/or- Stations
- Shower Curtain[s]
- Shower stall[s]
- Shower[s]
- Sink[s]
- Table[s]
- Toilet[s]
- Urinal[s]
- [Water] [Drinking] Fountain
- [Washable] Chair[s]
- [Washable] Walls



USE SURFACES:

- ABS [Acrylonitrile butadiene styrene] [plastic]
- Aluminum
- [Brushed] [Polished] Nickel
- [Brushed] Bronze
- Carpet (50 ppm FAC –or- 52 ppm sodium hypochlorite solution only), test in an inconspicuous spot first
- Glass
- Sealed Granite
- Hard, non-porous surfaces –or environmental surfaces
- Limestone
- Melamine
- Mirror
- [Polished] Chrome
- Polyacrylic
- Polycarbonate
- Polyethylene
- Polypropylene
- Slate
- Stainless Steel [304]
- Terrazzo
- To avoid possibility of discoloration, avoid prolonged contact of the 825 ppm FAC or 866 ppm sodium hypochlorite solution with certain metals (such as brass, steel), and marble surfaces.



Hydris™

Disinfectant, Sanitizer, Virucide, Fungicide, Mildewcide, Bactericide, Cleaner, Deodorizer

Active Ingredients:

Sodium Hypochlorite	0.0866%
Inert Ingredients	99.9134%
Total	100.00%

Available Chlorine: 0.0825% Free Available Chlorine FAC

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Harmful if absorbed through skin or swallowed Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Mixing this product with acid or ammonia will release chlorine gas.

Do not mix solution with other cleaning products.

Do not use solution with acidic toilet-bowl cleaners, or bathroom/shower cleaning products.

Do not use solution on wool or natural carpet fibers.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Solution(s) are efficacious for up to 7 days from filling. After 7 days, empty and refill with fresh solution. Always use a clean Hydris™ spray bottle when filling this product.

Solution can be used immediately or stored in a closed Ecolab approved container in a cool, dark area for a period of 5 months. Once opened within this time period, the solution must be used immediately.

Hydris™ Disinfectant Cleaner is intended for use in commercial, institutional and hospitality housekeeping. It cleans, deodorizes and kills germs in one step.

Hydris™ Disinfectant Cleaner is designed for use in

Hotel/motel housekeeping

Commercial building routine cleaning of hard surfaces and floors.

Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.

Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.

Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

Cleaning and disinfecting hospitals, assisted living facilities, long term care centers, nursing homes and medical clinics.

Spray solution onto hard, non-porous surface, thoroughly wetting surfaces, Hold sprayer 6-8 inches from the surface. Spread solution with a disposable, cotton or microfiber wipe, sponge, or cloth. Allow surface to remain wet for time indicated. No rinsing necessary.

BACTERICIDAL / DISINFECTANT in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria according to the AOAC Germicidal Spray Test in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Acinetobacter baumannii (ATCC 19606), *Acinetobacter baumannii* (MDR) (ATCC BAA-1605), *Escherichia coli* (ATCC 11229), *Klebsiella pneumonia* (ATCC 4352), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Serratia marcescens* (ATCC 14756), *Shigella flexneri* (ATCC 9380), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus aureus* (VISA) (ATCC 700788), *Staphylococcus aureus* (CA-MRSA) (ATCC BAA - 1683), *Staphylococcus aureus* (MRSA) (ATCC 33592), *Klebsiella pneumonia (Carapenum-resistant)* (ATCC BAA-1705), *Enterobacter aerogenes* (ATCC 13048),*Enterococcus faecalis* (ATCC 29212), *Streptococcus pyogenes* (ATCC 19615), *Shigella dysenteriae* (ATCC 29026), *Listeria Monocytogenes* (ATCC 7644).

BACTERICIDAL / DISINFECTANT in 10 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum when solution is sprayed onto hard, non-porous surfaces against the following pathogenic bacteria.

Enterococcus faecalis (VRE) (ATCC 51299) and *Escherichia coli* 0157:H7(ATCC 43895)

NON-FOOD CONTACT SURFACE SANITIZING in 1 minutes 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

NON-FOOD CONTACT SURFACE SANITIZING in 4 minutes at 273 ppm sodium hypochlorite (260 Free Available Chlorine) in 250 ppm hard water against the following pathogenic bacteria in the presence of 5% blood serum.

Staphylococcus aureus (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048).

VIRUCIDAL in 30 seconds at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Influenza A virus H1N1Strain (ATCC VR-1736), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Murine Norovirus (Strain MNV-1.CW1), Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Herpes Simplex Virus Type I (ATCC VR-733 Strain F), Herpes Simplex Virus Type II (ATCC VR-734, Strain G), HIV-1 (Strain HTLV-III_B).

VIRUCIDAL in 30 seconds at 273 ppm sodium hypochlorite (260 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum and 400 ppm hard water on hard, non-porous surfaces against the following organisms.

Rhinovirus type 37, strain 151-1 (ATCC VR-1147), Norovirus (Feline Calicivirus, strain F-9 ATCC VR-782 as Surrogate), Influenza A virus H1N1Strain (ATCC VR-1736),

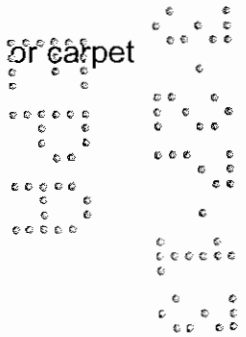
VIRUCIDAL in 5 minutes at 866 ppm sodium hypochlorite (825 ppm Free Available Chlorine) against the following viruses in the presence of 5% blood serum on hard, non-porous surfaces against the following organisms.

Adenovirus Type 5 (ATCC VR-5), Hepatitus B Virus (HBV), Human Coronavirus (ATCC VR-740), Respiratory Syncytial Virus (RSV) (ATCC VR-26), Rotavirus (Strain WA), Vaccinia Virus (ATCC VR-119).

This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1Influenza A virus.

FUNGICIDAL in 10 minutes at 866 ppm sodium hypochlorite 825 ppm Free Available Chlorine) according to the AOAC Fungicidal Test in the presence of 5% blood serum on hard, non-porous surfaces against *Trichophyton mentagrophytes* (ATCC 9533), and *Aspergilus niger* (ATCC 6275).

DEODORIZER Apply solution with sprayer, cloth, mop, auto-scrubber, or carpet extractor to surfaces harboring odor-causing bacteria.



STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

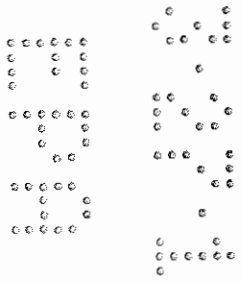
Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: RESIDUE REMOVAL INSTRUCTIONS: For containers less than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

Net Contents:



Manufactured by:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-[pending]
EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 5389-NC-(G) 1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V),

58046-TX-2 (X)

Superscript refers to first letter of date code

Optional Marketing Language

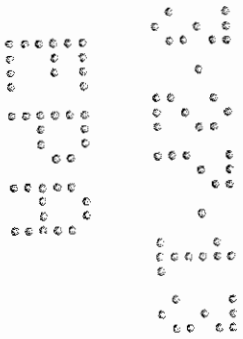
- Cleans every day dirt and soils from surfaces
- Deodorizes – or - Deodorizer
- Easy to use
- Eliminates odors
- Eliminates odors caused by [bacteria] [germs] [mildew]
- Leaves [bathroom(s)] [restroom(s)] [locker room(s)] [surfaces][clean and] sanitary
- Leaves behind a fresh clean smell – or - fragrance
- Low odor [formula – or- profile]
- No PPE [Personal Protective Equipment] required
- No rinsing necessary
- One-step cleaner [and disinfectant]
- Removes –or- eliminates odors [at the source]
- Streak-free [formula –or- clean]
- Effective against odor causing bacteria
- [This product is] VOC [Volatile Organic Compounds] compliant
- [This product] Contains no NPEs [Nonylphenol ethoxylates]
- [This product is] Phosphate free
- Leaves surfaces sanitized
- Sanitizer
- Sanitizes surfaces
- Sanitizes hard, nonporous surfaces
- Antibacterial [action]
- Bacteria-fighting - or – Germ-fighting formula
- Bactericide – or Bactericidal
- Restroom – or- bathroom disinfectant
- Broad spectrum disinfectant [cleaner]
- Cleans and disinfects
- Cleans and disinfects within 5 minutes Cleaner and disinfectant in one
- Cleans – and/or – disinfects [bathroom] [school] [classroom] [restroom] [locker room] [office] [work – or- office place] [environment] [place] [surfaces] [floors] [table – or- desk tops] [hard surfaces] [railings] -and/or- deodorizes
- Disinfects
- Disinfects and deodorizes by killing common [germs – or – bacteria] and controlling their odors
- Disinfects as it cleans
- Disinfects nonporous [hard] surfaces

- Easily [cleans] [deodorizes] [sanitizes] [disinfects]
- [Effective] disinfectant [in the presence of 5% serum load – or – organic soil]
- Germicide – or Germicidal
- Institutional disinfectant
- Kills 99.9% of bacteria –and/or – germs
- Kills 99.9% of bacteria – and/or germs commonly found in –or- on [the] [list any use site]
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] –and/or – destroy[s] [the] cold virus – and/or – flu virus – and/or – cold and flu virus[es] – and/or viruses that can cause cold - and/or flu
- Kill[s] – and/or – eliminate[s] – and/or - disinfect[s] – and/or- and/or – destroy[s] Methicillin-resistant Staphylococcus aureus [(MRSA)] –and/or – Community Acquired Methicillin-resistant Staphylococcus aureus [(CA-MRSA)]
- Kills cold and flu virus
- Kills germs while it cleans
- Kills Pandemic 2009 H1N1 Influenza A virus [(formerly called swine flu)]
- Multipurpose disinfectant
- One-step cleaner [and disinfectant]
- Antifungal
- Fungicidal –or- Fungicide
- Kills mold and mildew
- Kills athlete's foot fungus
- Mildewcidal –or- Mildewcide
- Removes –and/or – cuts through – and/or- tough on mold –and/or mildew
- Disinfectant
- Non-Food Contact Sanitizer
- Kills 99.9% of Bacteria in 60 seconds
- Effective in the Presence of 5% organic soil Contamination
- One-step Disinfectant/Cleaner
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Hospital Disinfectant
- Sanitizer
- Kills 99.9% of Bacteria
- Effective in the Presence of 5% organic soil contamination
- One-step Sanitizer/Cleaner
- One-step Germicidal Cleaner and Deodorant
- Effective One-step Sanitizer/Cleaner in hard water up 250 ppm hardness.
- Commercial building routine cleaning of hard surfaces, including glass/mirror surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.

- Cleaning high-touch surfaces such as door handles, tabletops, countertops, television remote-controls, headboards, doorknobs, etc.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.
- Commercial building routine cleaning of hard surfaces, and floors.
- Schools, universities, and campus routine, daily cleaning of hard surfaces and floors.
- Deodorizing areas in restrooms and toilet areas, behind and under sinks and counters, garbage containers, urinals, floors and other hard surfaces.

USE LOCATIONS: [Where to use this product] [For use around – or- in –or- throughout the]

- Assisted Living Facilities
- Athletic Facility[Facilities]
- Bathroom[s]
- Business[es]
- Commercials Building[s]
- Daycare Center[s] –or- Childcare Center[s]
- Fitness Center[s]
- Government Building[s]
- Health Club[s]
- Healthcare [facilities]
- Hospital[s]
- Hotel[s]
- Institutions
- Laboratories
- Lodging
- Locker Room[s]
- Long Term Care Center[s]
- Medical Facilities
- Motel[s]
- Office[s] [Buildings]
- Patient Care Area[s]
- Recreational Center[s] –or- Facility [Facilities]
- Retail Center[s]
- School[s] –an/or University[Universities] – and/or- Colleges



USE SITES: [For] Use on [hard,] [nonporous surface] – or - The product will not damage-or- harm

- [Bath] Tubs
- [Classroom] Desks
- Countertops
- Counter[s]
- Diaper Changing Table[s]
- Diaper Pail[s]
- [Door] Knobs
- Elevator[s]
- Fixture[s]
- Examination Tables –and/or- Beds
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- Glass –and/or- Mirror Surfaces
- Hard [Non-porous] Surfaces
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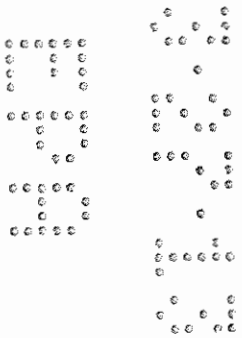
- [Water] [Drinking] Fountain
- [Washable] Chair[s]
- [Washable] Walls



USE SURFACES:

- ABS [Acrylonitrile butadiene styrene] [plastic]
- Aluminum
- [Brushed] [Polished] Nickel
- [Brushed] Bronze
- Carpet (50 ppm FAC –or- 52 ppm sodium hypochlorite solution only), test in an inconspicuous spot first
- Glass
- Sealed Granite
- Hard, non-porous surfaces –or environmental surfaces
- Limestone
- Melamine
- Mirror
- [Polished] Chrome
- Polyacrylic
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- Polyethylene
- Polypropylene
- Slate
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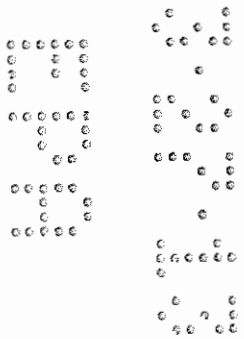

Pages 123-125 Confidential Statement of Formula may be entitled to confidential treatment